

ABS RESPONSE TO THE NATIONAL HEALTH MEASURES STUDY PRIVACY IMPACT ASSESSMENT

Introduction

The National Health Measures Study (NHMS) is a voluntary consent based biomedical collection of blood and urine samples from Australians aged 5 years and over (for urine) and 12 years and over (for blood). The NHMS aims to collect information from participants on selected biomedical markers of chronic disease, nutrition, and environmental measures to inform research and policy and ultimately to improve health outcomes for Australians.

This study will be conducted by the ABS, starting in 2022, on behalf of the Commonwealth Department of Health (the Department) as part of the [Intergenerational Health and Mental Health Study \(2020-2023\)](#). The ABS previously ran a similar study in the 2011-2013 [Australian Health Survey](#). The Study has been independently reviewed by an Ethics Committee to ensure the safety of participants.

The ABS welcomed advice from Maddocks throughout the process and is grateful for the final report. ABS has designed the study components while the Privacy Impact Assessment (PIA) was developed so ABS can address key privacy concerns in the final design for the study. The PIA identifies strong existing practices relating to management of personal information and notes development areas in the design of the NHMS.

Australian Health Biobank

In addition to the NHMS, the Australian Government will be establishing the Australian Health Biobank (AHB), with blood and urine samples stored indefinitely for use in approved research. The AHB is separate to the NHMS and will be managed by a Biobank Custodian (not the ABS) on behalf of the Department. Participation in the AHB is a voluntary consent based component and only includes adults aged 18 years and over. ABS interviewers will collect consent from NHMS survey respondents to participate in the AHB on behalf of the Biobank Custodian as part of the NHMS study.

While the establishment of the AHB is still being progressed, the ABS commissioned Maddocks to include relevant high-level privacy issues around the AHB in this review. This includes ABS' role in collecting the AHB consent for long term storage of samples and to perform data integration of biomedical sample results with ABS data such as the Multi-Agency Data Integration Project (MADIP).

Process 2 in the PIA includes a range of recommendations relating to the ongoing development of the AHB. The ABS has provided a response to Recommendation 5 and Recommendation 7 of the PIA, as these fall within its remit. The remaining recommendations will be provided to the Biobank Custodian to support development of the AHB once the Custodian is confirmed. The Biobank Custodian will provide a separate PIA in future addressing the AHB privacy settings.

ABS response to recommendations for the National Health Measures Study (NHMS) (PROCESS 1)

Recommendation 1 ABS implement further openness and transparency measures

Recommendation 1.1

We recommend the ABS consider publishing this PIA report, or a summary form outlining its findings and recommendations, on its website.

ABS response - Accepted

ABS will publish this PIA report and a response on the ABS website at the end of 2021 (before the NHMS commences) focused on Process 1 and ABS responsibilities within Process 2.

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.

ABS response - Accepted

ABS provides scripts for contact centre staff for all collections to support responses to participant questions and will work with the Biobank Custodian to provide information regarding the Australian Health Biobank.

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.

ABS response - Accepted

The ABS intends to work collaboratively with the Biobank Custodian to prioritise consistent, accurate, clear and informative messaging.

Recommendation 2 Revising nature of consent for the NHMS

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.

ABS response –Accepted

The biomedical test results alone from the NHMS are not of sufficient value without linkages to participant survey data or other ABS datasets (e.g. MADIP). Data linkage allows the NHMS data to be used to inform decisions and better support policy development.

The existing Tier 1 consent approach combining NHMS participation and data linkage consent reflects:

- 1) The requirement to link the biomedical test results with participant survey data to produce meaningful health statistics with contextual demographic information.
- 2) Alignment with existing MADIP arrangements for data linkage of some non-biomedical components of the broader Intergenerational Health and Mental Health Study that are collected under the *Census and Statistics Act 1905*.
- 3) The ABS commitment to reducing respondent and provider burden by using existing data where practical for the public good.
- 4) The requirement to explain all the consent options to participants for the NHMS and the AHB in an easy to understand manner within the allocated survey contact time.

The ABS opted to simplify the consent option for participants as unbundling these consents is operationally impractical, increasing survey contact time and respondent burden. The ABS recognises the sensitivity of data linkages and that it may be a concern for respondents. There are no consequences to the participant from the consent being bundled as it is a voluntary collection. As a result of the operational factors outlined above, the ABS will maintain the combined Tier 1 approach.

To support participants to make informed decisions about participating in the NHMS, the ABS will provide an explanation and transparency about this combined consent tier in a range of materials for participants. This will be provided by the interviewer and in a range of materials for participants. Participants will have an opportunity to ask questions and discuss participation with the interviewer - including about data linkage - prior to providing consent. If participants have remaining concerns after discussion with the interviewer they can decline to participate in the NHMS, and participants may also withdraw their consent to participate in the NHMS at any time by contacting the ABS.

The ABS will offer a range of additional information to consider outside of the Interview. This includes introductory approach materials, Collection Notices, Participant Information sheets and help line contact details. Information about data linkage will be provided through participant materials, supported by information on the [ABS website](#). Further information about the conditions under which data is linked to the MADIP is available in the [MADIP Privacy Impact Assessment](#). Data linkage information, including these links, are included in the NHMS Collection Notice via the ABS website.

Recommendation 3 – Preparing a simple collection notice for NHMS

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 Aboriginal Medical Services (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.

ABS Response – Partially Accepted

ABS will provide participant information sheets for all respondents when seeking consent to participate in the NHMS. All ABS collections also maintain participant web pages and contact details for further information. ABS provides a [Privacy Policy](#) statement on the website, as well as [collection notices](#) related to studies in operational phases.

The Collection Notice and Privacy Policy are only available in English. However, the ABS has limited options for language translation in interviews and printed materials. Where appropriate ABS will seek translation through a household member, or where available, an ABS Interviewer who can provide translation. Telephone Interpreter services are also available in some cases. ABS survey procedures allow for interviews to be terminated in the National Health Survey (NHS) and National Nutritional and Physical Activity Survey (NNPAS) where language barriers can't be resolved. This in turn would prevent an individual from being asked to consent to participation in the NHMS.

Each provider in the NHMS has publicly available Privacy Policies that cover the handling of personal information in line with APPs. Links to each provider's privacy policy are included in the collection notice of the study for participants.

Recommendation 4 – Protecting and strengthening privacy in arrangements with third parties

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).

ABS Response – Accepted

The contract with Sonic Pathology Australia ('Sonic Pathology') is now in place. The contract includes requirements around privacy, along with clauses on notifying the ABS if any personal information handling breaches occur. There are Key Performance Indicators (KPIs) set on these matters to measure performance.

The contract also outlines requirements for handling of personal information in line with the Australian Privacy Principles and the Privacy Act 1988. Participant information about the collection and handling of personal information are outlined in the collection notice for the study as well as other introductory materials.

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.

ABS Response – Accepted

ABS and Sonic Pathology have undertaken a trial of the NHMS to test processes for consent collection and the management of participant information between the two parties. The test has resulted in updated processes to reflect a wide range of scenarios. The contractual arrangements include the updated processes and must be followed. ABS and Sonic Pathology are both subject to data handling requirements under the Privacy Act 1988 and the Australian Privacy Principles. This is reinforced within Commonwealth Contract Terms.

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).

ABS response – Accepted

Contractual arrangements between the ABS and Sonic Pathology cover the disclosure of confidential information, outlining that any disclosure to any person other than the ABS requires written approval (Commonwealth Contract Terms CC22.C v6.4).

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.

ABS response – Accepted

Contractual arrangements prevent Sonic Pathology from using personal information for direct marketing purposes (Commonwealth Contract Terms CC22.C v6.4).

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 and any relevant AMS).

ABS response – Accepted

Where Sonic Pathology outsources any of the services for ABS or hires contractors to perform professional services, Sonic Pathology requires these subcontractors, under contract, to comply with the Privacy Act, or other relevant privacy legislation and, where applicable, [Sonic Healthcare Privacy Policy](#). The ABS has outlined requirements for handling personal information in the contract with Sonic Pathology.

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.

ABS response – Partially Accepted

Personal information will be collected by Sonic Pathology to facilitate the testing and management of participants' biomedical samples. This information may also be used to provide information about unexpected test results to the participants and/or their nominated health practitioner. For this purpose, Sonic Pathology will keep participants' names and addresses indefinitely. Personal information received by Sonic Pathology is managed in line with [Sonic Healthcare Privacy Policy](#) and the Privacy Act 1988. This information is included in the NHMS Collection Notice.

In addition, Sonic Pathology is required to destroy all unique identifiers and copies of consent forms at the end of the study.

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.

ABS response – Accepted

There are a series of KPIs relating to the transfer and receipt of data, and the quality thereof, in the contract. These will be monitored regularly, as will the data being returned, to ensure any issues are quickly rectified, and quality is maintained.

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.

ABS response – Accepted

The contract does outline data transfer processes and security requirements to protect personal information.

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.

ABS response – Accepted

The contractual arrangements between the ABS and Sonic Pathology include provisions regarding Sonic to report any suspected or actual breach, with the requirement to consult and comply with any reasonable directions set out by the ABS in handling any breach. This arrangement is set out by the Commonwealth Contract Terms within the contract (Commonwealth Contract Terms CC22.B v6.1), in line with the Privacy Act 1988 and the Australian Privacy Principles.

Recommendations relating to ABS involvement in the Australian Health Biobank (Process 2)

Recommendation 5

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.

ABS response - Accepted

The governance structure of the Biobank has been prepared by the Biobank Custodian and reviewed by a Human Research Ethics Committee. An independent Privacy Impact Assessment for the Biobank will also be commissioned, building on the recommendations of this initial Maddocks PIA review. The governance arrangements and Biobank PIA will outline the handling of research results and other personal information, including the role of the ABS.

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).

ABS response – Accepted

ABS will publicly refer participants on its website to the Biobank Custodian's website for information on the AHB and governance arrangements. Governance arrangements for the Biobank will be published on a website managed by the Biobank Custodian.

Recommendation 7

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

ABS Response – Accepted

ABS will provide separate participation information sheets and consent forms for the NHMS. The Biobank Custodian will also provide separate information and consent forms that clearly distinguish the differing consent being collected. The Biobank Custodian has prepared the consent form with each tier of consent separated on the form as recommended.