

Dr Lisa Fodero
Director, Health Consult Pty Ltd
3/86 Liverpool Street
Sydney NSW 2000
lisa.fodero@healthconsult.com.au

Re: Submission into the Department of Health's Development of a Framework for Secondary Use of My Health Record Data

Dear Dr Fodero,

Thank you for the opportunity to provide a submission into the development of a framework for the secondary use of data in the My Health Record system.

Positive Life NSW (Positive Life) is the state-wide peer based non-profit organisation that speaks for and on behalf of people living with and affected by HIV (PLHIV) in NSW. We provide leadership and advocacy in advancing the human rights and quality of life of all PLHIV, and to change systems and practices that discriminate against PLHIV, our friends, family and carers in NSW.

At Positive Life, we support enabling Australians to access, take control of and own their Health Records and data, where, when and how they wish. We acknowledge that by doing so, it improves the lives of individuals, particularly PLHIV by producing more efficient and effective health care outcomes. Further, the shared responsibility of data governance between the individual and the health system will build confidence and trust and generate good will. Also, we recognise that health data is sensitive, and believe that all sensitive data collated, whether identified or un-identified, 'for purpose' or linked, must have explicit and informed consent.

Our vision is that all PLHIV are able to live valued and meaningful lives, free from the impacts of stigma and discrimination, and contributing to the end of HIV transmission. We would like to commend the Australian Government Department of Health for their commitment to using health data for the purposes of systemic and individual-based outcomes, quality improvement, and for working with the community and health consumers to shape the development of this Framework. With this in mind, our submission (found at Attachment A) will concentrate on the collection, use and disclosure of My Health Record system data specifically for PLHIV.

If this submission requires additional information or clarification, I can be contacted on 0422 509 200 or at craigc@positivelife.org.au

Yours respectfully,



Craig Cooper
Chief Executive Officer

17 November 2017

ATTACHMENT A

Executive Summary - Positive Life believes that the paramount guiding principle to be included in the Framework is the principle of **'patient data sovereignty'**. While the nature of a nationally accessible electronic health record assumes some necessary sharing of record data from an operational and technical perspective, the legislation currently provides enormous scope for the System Operator to share health data "for any purpose", with (or in some cases without) the consent of the individual health recipient.

It is the view of Positive Life that the health data of all Australians, and in particular PLHIV, remains permanently owned by each individual and that no agency, company or individual should collect or appropriate the individual's health data, whether in whole or in part, without explicit, informed and ongoing consent. This position is based on the principle of individual agency and self-determination, and should be seen to be applicable regardless of how the data is collected, analysed and disseminated, and whether the data is to be used in an identified or de-identified manner.

Background - The My Health Record system (previously the Personally Controlled Electronic Health Record (PCEHR) system), was created with the intention and primary purpose of improving the quality and safety of healthcare, reducing waste and inefficiency, and improving health outcomes for individuals, while giving Australian health consumers better access to their own health information, promoting consumer participation, and supporting self-management and informed decision-making. While Positive Life acknowledges this may be the intention and primary purpose of the My Health Record system, the intent does not justify the potential risks that could result from a lack of data sovereignty and secondary uses of PLHIV's health data.

Consent and Privacy - According to a statement from the National Health & Medical Research Council: "Consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it."¹ At the time of signing up to the My Health Record system, the default setting of each record is set 'open' and exists in its most shareable state. While we acknowledge that the individual health record holder is able to self-manage the security of their accounts by restricting parts of the record for privacy purposes, Positive Life is concerned that the default starting position already implies a level of consent to the sharing of personal health data which is arguably neither explicit, nor informed. As such, Positive Life views that each individual health record at the time of its creation, exists in a state of uninformed (or absent) consent, and take the view that applying this level of consent to the secondary use of My Health Record data, is deeply problematic.

Positive Life strongly recommends that all My Health Record accounts are created initially in the highest restrictive privacy setting, where an individual record holder has the option to change those privacy settings. Prior to that change, the individual must be fully informed of any potential risks to usage of the data, and what personal health information could become available to researchers and other third parties, should they proceed. We believe that every individual should be able to decline from participating in research, or to personally decide what information of theirs, sensitive or otherwise, is available to researchers and other third parties. Further, we believe that people should be able to delete sections of the record or the entire record if they feel it is no longer of benefit to them or no longer serves a purpose.

Positive Life strongly recommends that all My Health Record accounts are only used for secondary purposes when explicit, informed and ongoing consent is provided, and that alternatives to participation, specifically - in the form of an 'opt in' framework for secondary use of data - be the

¹ See: <https://www.nhmrc.gov.au/book/chapter-2-2-general-requirements-consent>

default setting for all accounts. We recommend that all My Health Record account holders have the ability to 'opt-in' to the secondary use of their health data from sign up and current account holders be switched to such a system. Further, if consent is provided and a person opts-in to the secondary use of data, if this data is de-identified and linked for other reasons (not the original consented purpose) or on-sold for research or commercial interests, this ought to be automated into the system and people notified in each and every occurrence.

Positive Life agrees with the National Health & Medical Research Council (NHMRC)'s statement: "While an opt-out approach makes it possible for people to make an informed choice about their participation, this choice can only be made if participants receive and read the information provided, and they understand that they are able to act on this information in order to decline to participate. Importantly, the opt-out approach fails to constitute consent when applying commonwealth privacy legislation to the handling of sensitive information, including health information."² While acknowledging that all record holders will be afforded an opportunity to 'opt-out' of the My Health Record system, Positive Life has concerns that the secondary use of My Health Record data will create unacceptable barriers to participation in the program and ultimately, to an individual's primary health care.

Secondary Uses - We recognise that the law currently reflects the general principle that, in certain circumstances, the individual's privacy and information can be forfeited for the greater good of community health and research. However, Positive Life does not believe that the secondary use of private health data, particularly commercialisation (whether in whole or in part) is in any way acceptable, and believe that commercialising such data erodes trust and integrity between individuals, their health care providers and the health system more generally. Further, we believe that the mass imposition of such a data system on the entire population, mining highly sensitive health information which is then collated, shared and commercialised by the government and private entities, will be of great concern to many Australians, in particular PLHIV.

Anecdotal feedback from numerous PLHIV and other health consumers who are current My Health Record account holders has revealed that many were unaware that their personal and sensitive health data would become available for 'secondary use' at any stage, least of all, presently. This suggests that explicit, informed, and ongoing consent has not occurred, and that due to the evolving nature of the E-health record system since its inception in 2012, this issue will have practical, privacy and ethical impacts that will require a policy response before the national rollout. We do not believe that individuals already signed up to the My Health Record service, are informed and have provided consent for the secondary use of private health data either explicitly or implied. We request that the Government, through the development and implementation of the framework, ensure these concerns and considerations are addressed accordingly.

Only in the case of explicit, fully informed and ongoing consent, does Positive Life believe that the secondary use of My Health Record data is to occur, that Australian government agencies and select Australian not-for-profit entities should have access to the data. 'Secondary uses' should be limited to: the development of new health services and/or improvements to existing health services; the development of new health care products/services and/or improvements to existing products/services (e.g. pharmaceuticals, medical devices, diagnostic tests, etc.); and the development of government health policy and/or programs. We believe that the evaluation of individual health interventions and health programs are best acquired through direct engagement of individuals through health consumer-based qualitative feedback.

² See: <https://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research-2007-updated-december-2013/chapter-2-3-qualif>

Positive Life believes that any secondary use should not come at the cost of ensuring optimal and efficient health care. We believe that releasing data for secondary uses will prove a challenge in particular to vulnerable populations most in need of health services, such as PLHIV.

Confidentiality - *Positive Life understands there are provisions in the My Health Records Act 2012 for the System Operator, or healthcare professionals, to reveal to authorities details of any criminal behaviour referenced in a My Health Record account. We have concerns that this information, divulged in confidentiality to a primary healthcare provider, can be passed on to authorities or used for a variety of 'secondary uses'. Positive Life has concerns that active use of private health data for such purposes may lead to the benign or active surveillance of a given individual or population (such as PLHIV, sex workers, people who use or inject drugs, and other vulnerable populations), therefore highlighting significant legal, privacy and ethical risks for all involved. We do not see sufficient protections for vulnerable and marginalised populations included in the current legislation, nor recommended as part of this consultation, and request the government seeks to amend this deficit during the development and implementation of the framework.*

PLHIV are a significantly marginalised population and encounter ongoing stigma and discrimination in the community. The linkage of data has the potential to re-identify PLHIV and the risk to safety and wellbeing is considered too high for our peoples. As such, Positive Life does not support the linkage of data between My Health record and other datasets, particularly for the purpose of secondary uses of that data. Positive Life believes that confidentiality of an individual's health data is paramount and would strongly support the complete de-identification of data, suppression criteria to ensure smaller data cells are not released, and that statistical linkage keys be used to maintain the confidentiality and privacy of patient level data.

Commerciality and Coercion - *Positive Life is opposed to the use of My Health Record data for commercial purposes under all circumstances, including where commercial benefits are not the main purpose of the data collection. We believe that by allowing such activities to take place, it both actively and passively undermines the primary health purpose and benefits of the program. As such, we do not support any direct marketing to health consumers or healthcare providers by commercial entities.*

We are concerned about the potential for coercive behaviour by agencies and/or sectors such as the Health or Life Insurance industries, who may demand access to the My Health Record system in return for lower premiums. This exploitation of data for the purposes of commercial gain must not be facilitated by government, and as such, we believe that obtaining secondary data for commercial benefit should be explicitly banned.

We also do not support the recruitment of patients to clinical trials via the My Health Record system, as we believe that prospective participants may feel coerced or not fully comprehend, for example, by the very nature of unsolicited material (electronic or other) arriving via the government-run system. We believe if an individual wishes to participate in a clinical trial, they will make themselves available to such opportunities through their primary healthcare provider or research networks.

Accountability and Oversight – *Any primary or secondary data users and custodians must adhere to an accountability framework and with all relevant policies and legalisation from all jurisdictions, to ensure integrity of the system in releasing data for secondary purposes. We do not support the collection and use of data without a legitimately clear and beneficial purpose to the public. If this threshold has been met, we support the efficient and timely approval, extraction and release of data, with an explicit expectation of a timely public release of a findings report and/or publication.*

Positive Life believes that any governance committee overseeing the secondary use of My Health Record system data should not rest solely with one agency (for example the Department of Health), but be integrated with consumers, representative NGOs and non-commercial healthcare bodies, and independent experts. We would like to stress the importance of including health consumers' and healthcare bodies' voices to the success of the My Health Record program and secondary data use oversight. We strongly recommend that the voice of consumers make up a substantial quota of any committee, to ensure that the interests of health consumers take precedence over research and commercial priorities.

As is best practice and in line with the National Human Medical & Research Council standards on research involving humans, Positive Life agrees that ethics committee approval must be sought and given for any secondary data use. We believe all data that is released from the My Health Record system, must only be in the form of de-identified data and cannot present an unacceptable risk to an individual's privacy. No identifiable data from the My Health Record system should be available for secondary uses.

Positive Life believes that there should be a public register that details the organisations and individuals that have requested data, the purpose, nature and status of the data request, compliance reports and any publications that have resulted from the use of such data. Every approved user of the My Health Record system should sign a confidentiality protection agreement and that legal penalties must be strictly enforced for the misuse of data. We support frequent, random audits to ensure data usage complies with the approved purpose. Further, we support a compulsory requirement for end of project and annual compliance reports from every requesting agency, company or individual that is granted access to data for secondary use. Details of the funding arrangement (amount and sources) for the organisations, individuals and projects, as well as financial or other relevant declarations of interest of researchers, sponsors or institutions, should be made publicly available on the register for the purpose of transparency.

Conclusion - *Positive Life's position is that the My Health Record system, of which its purpose is to deliver better outcomes in Primary healthcare, will be undermined by the extraction of data for secondary uses. We believe the best way to ensure active and ethical participation in the My Health Record program is to provide account holders with the opportunity to express explicit, informed and ongoing consent, while providing an 'opt in' framework for secondary use of their private health data.*