Cyberspace Law and Policy Centre
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Health and Research Privacy

Response to the Australian Law Reform Commission (ALRC) Privacy Report 108 Pt H

Submission to the Australian Government

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This submission is to the Department of Prime Minister and Cabinet as part of of its post-ALRC consultation on privacy law reform. This submission was informed by the discussion at the Health Privacy Forum consultation meeting held on 3 February in Sydney. This submission complements the Centre's three other submissions - on the Unified Privacy Principles (UPPs); on Credit Reporting, and on other ALRC recommendations.

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60. Regulatory Framework for Health Information		
General		As with the proposed regulation of credit reporting, the ALRC's recommendations for health privacy are not primarily about providing extra protection for sensitive information. Derogations from the UPPs are seen as necessary to accommodate other private and public interests that compete with privacy. Thus collection, use and disclosure that would not be possible without consent under the UPPs for other categories of sensitive information are expressly allowed for health information. Some extra safeguards are then applied. A clear understanding of this starting point is required as it should inform judgements about the privacy 'risk' inherent in some of the proposed exceptions and derogations, particularly if available to a wider range of data users as a result of other proposed changes. It should also be recognised that individuals' expectations about privacy may differ between different contexts. Many individuals may expect and welcome information sharing within a relatively tightly defined 'treatment team' (not necessarily geographically collocated or within a single entity). But many will be less accepting of wider sharing of

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		identifiable personal information for 'public interest' purposes such as benefit administration, service planning and research (see separate submissions below on the ALRC's research recommendations). The ALRC recommendations for health privacy do not distinguish adequately between these different contexts, resulting in an uneasy compromise. By suggesting the same provisions and tests for all secondary uses and disclosures, restrictions are placed on information sharing for direct health care purposes which may be unnecessary, while derogations from the normal application of privacy principles are allowed, inappropriately, for administrative purposes to which the default UPPs could and should apply.
regulations	**Recommendation 60–1** Health information should be regulated under the general provisions of the *Privacy Act*, the model Unified Privacy Principles (UPPs), and regulations under the *Privacy Act*—the new *Privacy (Health Information) Regulations.* The new *Privacy (Health Information) Regulations* should be drafted to contain only those requirements that are different or more specific than provided for in the model UPPs.	Regulations are too easy to change if left to normal processes. Key aspects of the health privacy regime should remain in the Act. Other aspects can be left to Regulations provided there are statutory consultative processes including public hearings. If Regulations are able to weaken the protection offered by the Act it is essential that any proposed changes are not dealt with behind the closed doors of AHMAC meetings and then by only the normal Regulation making mechanisms, which offer little opportunity for public debate.

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		Any health privacy provisions in the Act or Regulations should follow the sequence of the UPPs.
UPPs and the amendments	**Recommendation 60–2** The Office of the Privacy Commissioner should publish a document bringing together the model Unified Privacy Principles (UPPs) and the additions set out in the new *Privacy (Health Information) Regulations*. This document should contain a complete set of the model UPPs as they relate to health information.	Support
guidelines	**Recommendation 60–3** The Office of the Privacy Commissioner—in consultation with the Department of Health and Ageing and other relevant stakeholders—should develop and publish guidelines on the handling of health information under the *Privacy Act* and the new *Privacy (Health Information) Regulations*.	Support, subject to our generic caution about placing too much reliance on Privacy Commissioner guidance, which unless binding has limited value.
61. Electronic Health Information Systems		
Unique Healthcare Identifiers	**Recommendation 61–1** If a national Unique Healthcare Identifiers (UHIs) or a national Shared Electronic Health Records (SEHR) scheme goes forward, it should be established under specific enabling legislation. This legislation should address information privacy issues, such as: (a) the nomination of an agency or organisation with clear responsibility for managing the respective systems, including the personal information contained in the systems; (b) the eligibility criteria, rights and requirements for participation in the UHI and SEHR schemes by health consumers and health service providers, including consent requirements; (c) permitted and prohibited uses and linkages of the personal	Support. The specific legislation should also address the key issue of consent, with the starting point being the 2006 COAG commitment to a consent-based national EHR system (http://www.coag.gov.au/coag_meeting_outcomes/2006-02-10/index.cfm#reform) In any consideration of consent, regard should be had to issues such as 'express vs implied' and 'bundled' consent – see our submissions on the UPPs and other ALRC recommendations. It should not be possible, for example, to rely on (in effect mandatory) acceptance of

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	information held in the systems; (d) permitted and prohibited uses of UHIs and sanctions in relation to misuse; and (e) safeguards in relation to the use of UHIs, including providing that it is not necessary to use a UHI in order to access health services.	general tems and conditions of applying for a Medicare rebate to give consent to an unlimited range of data sharing, matching and linkage of health information with Medicare Australia. In an Electronic Health Records context, consideration should be given to options for individuals to expressly deny access to specified information and/or to specified persons, as this may often be the objective of individuals, who are otherwise willing to give a general 'default' consent to sharing. Consideration should also be given to allowing individuals appropriate access to audit trails in any SEHR system, so that they can monitor access to their information. This would provide an important accountability tool and also help to re-assure individuals when seeking their consent for inclusion.
62. The *Privacy Act* and Health Information		
	Recommendation 62–1 The definition of 'health information' in the *Privacy Act* should be amended to make express reference to the *physical, mental or psychological* health or disability of an individual.	Support
	Recommendation 62–2 The *Privacy Act* should be amended to define a 'health service' as: (a) an activity performed in relation to an individual that is intended or claimed (expressly or otherwise) by the individual or the service	May require a narrower definition to avoid commercial organisations being able to take advantage of the various proposed derogations from the UPPs. Broad definitions of health information and health

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	provider to: (i) assess, predict, maintain or improve the individual's physical, mental or psychological health or status; (ii) diagnose the individual's illness, injury or disability; or (iii) prevent or treat the individual's illness, injury or disability or suspected illness, injury or disability; (b) a health-related disability, palliative care or aged care service; (c) a surgical or related service; or (d) the dispensing on prescription of a drug or medicinal preparation by a pharmacist.	service are desirable in the context of additional protection, but not always in the context of additional exceptions and derogations. Specifically, the Act should expressly exclude health insurance from the definition of 'health service', which might arguably fit within the proposed category (a)(i). See also our comments below on Rec 63-9 – which does not in our view exclude health insurers from gaining the benefit of the health privacy derogations, even if they are not themselves providing a health service. Consideration should be given to whether activities relating to non-prescription medication by pharmacists, while clearly outside category (d), would nonetheless qualify as a health service under category (a)(i). If so, is this an intended outcome? Assurances should be given that the proposed derogations from the limits on use and disclosure of health information would only vary the effect of UPP 5 (Use and Disclosure) and not limit the application of UPP 6 (Direct Marketing) which would continue to apply to health service providers. One way of limiting unintended consequences of the broad definition of health service would be to introduce a second test into at least some of the provisions relating to collection, use and disclosure of health information for the purposes of a health service. This test would be that the activity must be directly related

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		to the provision of health care to individuals.
63. Privacy (Health Information) Regulations		
collection of family medical history	**Recommendation 63–1** The new *Privacy (Health Information) Regulations* should provide that, in addition to the other provisions of the 'Collection' principle, an agency or organisation that provides a health service may collect health information from an individual, or a person responsible for the individual, about third parties when: (a) the collection of the third party's information is necessary to enable the health service provider to provide a health service directly to the individual; and (b) the third party's information is relevant to the family, social or medical history of that individual.	Support, but the variation should be in the Act not in Regulations. This recommendation addresses a specific issue that has caused difficulty in the past and has led to Public Interest Determinations under the Act allowing derogation from the NPPs.
reasonable expectation	**Recommendation 63–2** The new *Privacy (Health Information) Regulations* should provide that, in addition to the other provisions of the 'Collection' principle, an agency or organisation that is a health service provider may collect health information about an individual if the information is necessary to provide a health service to the individual and the individual would reasonably expect the agency or organisation to collect the information for that purpose.	Support, but the variation should be in the Act not in Regulations. It is not clear why the ALRC considers that this additional exception should apply to health information/health services but not to other sensitive information (in which case it could have been incorporated in UPP 2.5).
disclosure to a person responsible	**Recommendation 63–3** National Privacy Principles (NPPs) 2.4 to 2.6 — dealing with the disclosure of health information by a health service provider to a person who is responsible for an individual —should be moved to the new *Privacy (Health Information) Regulations*. The new regulations should provide that, in addition to the other provisions of	Support, subject to our generic suggestion that any Regulations be subject to statutory consultative processes including public hearings. We note than NGOs with 'front line' experience of

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	the 'Use and Disclosure' principle, an agency or organisation that provides a health service to an individual may disclose health information about the individual to a person who is responsible for the individual, if the individual is incapable of giving consent to the disclosure and all the other circumstances currently set out in NPP 2.4 are met. In addition, the new regulations should: (a) be expressed to apply to both agencies and organisations; (b) not refer to a health service provider who may make a disclosure under these provisions as a 'carer'; and (c) define 'a person who is responsible for an individual' as: (i) a parent, child or sibling of the individual; (ii) a spouse or de facto partner of the individual; (iii) a relative of the individual who is a member of the individual's household; (iv) a substitute decision maker authorised by a federal, state or territory law to make decisions about the individual's health; (v) a person who has an intimate personal relationship with the individual; (vi) a person nominated by the individual to be contacted in case of emergency; or (vii) a person who is primarily responsible for providing support or care to the individual. In considering whether to disclose an individual's health information to a person who is responsible for an individual and who is under the age of 18, a health service provider should consider, on a case-by-case basis, that person's maturity and capacity to understand the information.	dealing with third party representatives have concerns about the wide variety of different circumstances which have been treated in the same way in this Recommendation – e.g. a person nominated as a contact in case of emergency (c)(vi) should not be assumed to have the same status or privileges in relation to health information as a parent (i) or substitute decision maker authorised by law (iv); while 'a person who has an intimate relationship' is too imprecise (and in many cases unknowable) to be a useful category. Further consideration of this provision is required. Consideration should also be given to allowing individuals to nominate in advance specific individuals who they would *never* want to be allowed access to health information about them in circumstances this provision is intended to cover. Any such preferences should be required to be respected unless overridden by law.

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'de facto partner'	**Recommendation 63–4** The *Privacy Act* should be amended to provide a definition of 'de facto partner' in the following terms: 'de facto partner' means a person in a relationship as a couple with another person to whom he or she is not married.	Support
genetic information	**Recommendation 63–5** The new *Privacy (Health Information) Regulations* should include provisions similar to those set out in National Privacy Principle 2.1(ea) on the use and disclosure of genetic information where necessary to lessen or prevent a serious threat to the life, health or safety of a genetic relative. These regulations should apply to both agencies and organisations. Any use or disclosure under the new regulations should be in accordance with rules issued by the Privacy Commissioner.	Support. We note that the current requirement for the threat to be imminent as well as serious (in NPP 2.1(ea) has been omitted. We refer to our submission on the UPPs in which we suggest an alternative test: "that there is an urgent need for the use or disclosure such that any other means of compliance with this principle is not practicable in the circumstances." We assume that the rules referred to in this recommendation would be binding Rules given statutory effect by the Act (see our general submission on the proposed regulatory structure). It should be made clear whether this provision, if included, would apply retrospectively.
subject access	**Recommendation 63–6** The new *Privacy (Health Information) Regulations* should provide that, in addition to the other provisions of the 'Access and Correction' principle, if an individual is denied access to his or her own health information by an agency on the basis that providing access would, or could reasonably be expected to, endanger the life or physical safety of any person, or by an organisation on the basis that providing access would be reasonably likely to pose a serious threat to the life or health of any individual: (a) the agency or organisation must advise the individual that he or she may nominate a suitably qualified health service provider ('nominated	Support. This is a more specific and detailed version of the general requirement in UPP 9.3. It is justified given the importance of a right of access to personal health information and the likelihood of this exception being applicable in a health context. Condition (c) should however include a requirement that the grounds for objection to nomination be 'reasonable', to avoid objections on grounds such as competition between providers or personal dislike. Consideration should be given to introducing reporting

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	health service provider') to be given access to the health information; (b) the individual may nominate a health service provider and request that the agency or organisation provide the nominated health service provider with access to the information; (c) if the agency or organisation does not object to the nominated health service provider, it must provide the nominated health service provider with access to the health information within a reasonable period of time; and (d) the nominated health service provider may assess the grounds for denying access to the health information and may provide the individual with access to the information to the extent that the nominated health service provider is satisfied that to do so, in the case of an agency, would not, or could not be reasonably expected to, endanger the life or physical safety of any person and, in the case of an organisation, would not be reasonably likely to pose a serious threat to the life or health of any individual. If the agency or organisation objects to the nominated health service provider and refuses to provide the nominated health service provider with access to the information, the individual may nominate another suitably qualified health service provider, or may lodge a complaint with the Privacy Commissioner alleging an interference with privacy.	requirements (to the Privacy Commissioner) on agencies and organisations objecting to nominations – both as a disincentive and as an accountability device. The Privacy Commissioner should be required to report publicly on the volume of 'objections to nominations'.
organisational changes	**Recommendation 63–7** The new *Privacy (Health Information) Regulations* should provide that, in addition to the other provisions of the 'Data Security' principle, where an agency or organisation that provides a health service is sold, amalgamated or closed down, and an individual health service provider will not be providing health services in the new agency or organisation, or an individual health service provider dies, the provider, or the legal representative of the provider,	Support – this specific requirement is justfified in the interests of individuals being able to participate in decisions about access to their health information when organisational circumstances change. Consideration should be given to extending this obligation to circumstances where the same individual

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	must take reasonable steps to: (a) make individual users of the health service aware of the sale, amalgamation or closure of the health service, or the death of the health service provider; and (b) inform individual users of the health service about proposed arrangements for the transfer or storage of individuals' health information.	health service provider will continue in the new agency or organisation, given the other proposals which will allow for access, without consent, to a wide range of associated health professionals and support staff. Individuals may well be uncomfortable with the changed organisational circumstances whether or not the individual provider is continuing – requiring notice to be whenever all such changes take place would at least give indviduals the opportunity to review the arrangements, and perhaps invoke the proposed right to request a transfer (Rec 63-8). The obligation should also apply in circumstances of dis-aggregation; e.g. where a health service provider breaks up into two or more separate legal entities. Consideration should be given to linking this obligation to a requirement to notify health professional registration boards about changing organisational circumstances – we understand such a requirement already applies in some States. It is not clear why this recommendation is linked specifically to the Data Security principle, as it supports several of the proposed UPPs.
transfer of services	**Recommendation 63–8** (a) The new *Privacy (Health Information) Regulations* should provide that, in addition to the other provisions of the 'Access and Correction' principle, where an individual requests that an agency or organisation that is a health service provider transfers the individual's health information to another health service provider, the agency or organisation must respond within a reasonable time and	Support

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	transfer the information. (b) Other elements of the 'Access and Correction' principle relating to access should apply to a request for transfer from one health service provider to another, amended as necessary.	
general derogation from UPPs for Collection, Use and Disclosure of health information	**Recommendation 63–9** The new *Privacy (Health Information) Regulations* should provide that, in addition to the other provisions of the 'Collection' principle and the 'Use and Disclosure' principle, an agency or organisation may collect, use or disclose health information where necessary for the funding, management, planning, monitoring, or evaluation of a health service where: (a) the purpose cannot be achieved by the collection, use or disclosure of information that does not identify the individual or from which the individual would not be reasonably identifiable; (b) it is unreasonable or impracticable for the agency or organisation to seek the individual's consent before the collection, use or disclosure; and (c) the collection, use or disclosure is conducted in accordance with rules issued by the Privacy Commissioner.	It should be clear that this recommendation is for a derogation from the 'default requirements of the UPPs, including UPP 2.5, which impose a higher collection standard on all 'sensitive' information as defined in the Act (to include health information) This is an example of the proposed Regulations 'weakening' the privacy protection for health information/health services, in order to facilitate other health care objectives, purported to be in the interests of individuals. Any such proposals need to be carefully assessed as to the real reasons for derogating from the UPPs. These reasons may include efficiency and convenience of health care professionals, and efficiency of health benefit administration, with at best an indirect benefit to individuals. While these other 'public interests' may justify the derogation, they should not be presented as necessarily in the interests of indivduals, particularly if they also involve a loss of privacy, autonomy or control. Like NPP 10.3, this specific proposal is for a very significant derogation from the default principle of consent for collection, use and disclosure of health

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		information. We submit that the derogation should remain in the Act rather be provided in Regulations. The further submissions below apply whether the provision is in the Act or in Regulations. There is no limitation in this recommendation to health service providers. Is it intended that agencies and organisations that are not themselves providers of health services should obtain the benefit of these derogations if they are involved in 'funding, management, planning, monitoring or evaluation of a health service provided by another entity'? If so, this would appear to give, for example, health insurers the benefit of the special health privacy regime. We do not believe this is intended, but it should be expressly ruled out by adding 'an agency or organisation *that is a health service provider ...*' The word 'and' should be inserted at the end of (a), to make it clear that *all* of the conditions (a)-(c) must be satisfied (as in the current NPP 10.3). The addition of 'unreasonable' as well as 'impracticable' in (b) is dangerous as it opens up the prospect of self-interested judgments by agencies and organisations which undermine the intended stringency of the test to be applied. To avoid this, it should be expressly provided that the rules to be issued by the Privacy Commissioner must include rules concerning what may be considered

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		'unreasonable' for the purposes of (b). It is implicit that the health privacy Regulations would not provide for the separate purpose of research (which is currently addressed in NPP 10.3 alongside 'funding, management, planning, monitoring, or evaluation of a health service'). The ALRC's proposal is that research use of *any* personal information, including 'sensitive information' and the sub-set of 'health information', will be governed by research exceptions to UPPs 2 & 5 , with a separate set of Research Rules (see below). We suggest that the Act should expressly provide a definition of 'human research' and make it clear that the collection, use and disclosure of health information for 'human research' was *outside* the scope of the special provisions for 'funding, management, planning, monitoring, or evaluation of a health service' (see separate submissions below in relation to the ALRC research recommendations).
rules	**Recommendation 63–10** The *Privacy Act* should be amended to empower the Privacy Commissioner to issue rules in relation to the handling of personal information for the funding, management, planning, monitoring, or evaluation of a health service.	Support, subject to adequate consultation requirements, which should be modelled on Part VI (Public Interest Determinations), including public notice and hearings. See submission above in relation to the rules needing to cover 'unreasonable'.

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65. Research: Recommendations for Reform		As with the proposed regulation of credit reporting, the ALRC's recommendations for privacy and research are not primarily about providing extra protection. Derogations from the UPPs are seen as necessary to accommodate other private and public interests that compete with privacy. Thus collection, use and disclosure that would not be possible under the UPPs are expressly allowed for research purposes . Some extra conditions and safeguards are then applied. A clear understanding of this starting point is required as it should inform judgements about the privacy 'risk' inherent in some of the proposed exceptions and derogations. The ALRC is incorrect in asserting (in paragraphs 64.1-2), that the current NH&MRC Guidelines regime applies to *any* personal information. The s 95 guidelines apply to agencies only, and to any personal information, but only when used for *medical* research, whereas the s 95A guidelines apply to organisations only, but cover health research more generally, and also a wide range of other health service purposes, but only in relation to the use of *health* information.
	Recommendation 65–1 (a) The Privacy Commissioner should issue one set of rules under the research exceptions to the 'Collection' principle and the 'Use and Disclosure' principle to replace the *Guidelines under Section 95 of the Privacy Act 1988* and the *Guidelines*	Support, subject to adequate consultation requirements, which should go beyond the ALRC's proposed requirement to consult in (b), and the current arrangements for ss 95 and 95A Guidelines.

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	Approved under Section 95A of the Privacy Act 1988. (b) The Privacy Commissioner should consult with relevant stakeholders in developing the rules to be issued under the research exceptions to the 'Collection' and 'Use and Disclosure' principles—that is, the 'Research Rules'. (c) Those elements of the *National Statement on Ethical Conduct in Human Research* dealing with privacy should be aligned with the *Privacy Act* and the Research Rules to minimise confusion for institutions, researchers and Human Research Ethics Committees.	The consultation requirements for rules should be modelled on Part VI (Public Interest Determinations), including public notice and hearings.
	Recommendation 65–2 The *Privacy Act* should be amended to extend the arrangements relating to the collection, use or disclosure of personal information without consent in the area of health and medical research to cover the collection, use or disclosure of personal information without consent in human research more generally.	This would be given effect though the adoption of the ALRC recommendations for research exceptions to UPPs 2 & 5, supported by the new Research Rules. This is a major departure from the current regime, which limits the research exception to medical research (in relation to any personal information handled by agencies – s 95) and more general health research (but only in relation to health information handled by organisation – NPP10.3 and s 95A). Without some very strict guidelines as to what constitutes 'human research' that should gain the benefit of the derogation from the consent requirement, this would be a major weakening of the current level of privacy protection. Without any limiting definitions, a wide range of commercially oriented 'research' could qualify, without significant public benefit or interest, particularly if the additional 'unreasonable' excuse is added (see above

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		and below). The current NH&MRC definition of human research in its 2007 National Statement is clearly relevant, but is designed from a health related perspective, and may not be suitable for the intended broader application of the Privacy Act Research Rules. We submit that the current restriction of s 95A to 'research, or the compilation or analysis of statistics, relevant to public health or public safety' may be an appropriate limitation that should be carried over into the proposed new Research Rules.
	Recommendation 65–3 The *Privacy Act* should be amended to provide that 'research' includes the compilation or analysis of statistics.	Support, subject to our other submissions about the research exceptions.
	Recommendation 65–4 The research exceptions to the 'Collection' principle and the 'Use and Disclosure' principle should provide that, before approving an activity that involves the collection, use or disclosure of sensitive information or the use or disclosure of other personal information without consent, Human Research Ethics Committees must be satisfied that the public interest in the activity outweighs the public interest in maintaining the level of privacy protection provided by the *Privacy Act*.	This proposal assumes that the Privacy Commissioner will carry a requirement for Ethics Committee approval over from the ss 95 and 95A Guidelines into the new Research Rules. We submit that this should be made express in the legislation. See also our submission below about the availability of Ethics Committees.
	Recommendation 65–5 The research exceptions to the 'Collection' principle and the 'Use and Disclosure' principle should include a provision stating that it must be 'unreasonable or impracticable' to seek consent from individuals to the collection, use or disclosure of their	See our submissions above and below in relation to the dangers of including 'unreasonable' in the test, and the need for rules about this in the Research Rules.

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	personal information before that information may be used without consent for the purposes of research.	
Human Research Ethics Committee	**Recommendation 65–6** The National Health and Medical Research Council, the Australian Research Council and Universities Australia should amend the *National Statement on Ethical Conduct in Human Research* to state that, where a research proposal seeks to rely on the research exceptions in the *Privacy Act,* it must be reviewed and approved by a Human Research Ethics Committee.	This proposal assumes that the Privacy Commissioner will carry a requirement for Ethics Committee approval over from the ss 95 and 95A Guidelines into the new Research Rules. We submit that this should be made express in the legislation. See also our submission below about the availability of Ethics Committees.
reporting requirements	**Recommendation 65–7** The Privacy Commissioner, in consultation with relevant stakeholders, should review the reporting requirements imposed under the *Privacy Act* on the Australian Health Ethics Committee and Human Research Ethics Committees. Any new reporting mechanism should aim to promote the objects of the *Privacy Act*, have clear goals and impose the minimum possible administrative burden to achieve those goals.	Support, but see also our submission below about the availability of Ethics Committees.
derogation from collection principle	**Recommendation 65–8** The research exception to the 'Collection' principle should provide that an agency or organisation may collect personal information, including sensitive information, about an individual where all of the following conditions are met: (a) the collection is necessary for research; (b) the purpose cannot be served by the collection of information that does not identify the individual; (c) it is unreasonable or impracticable for the agency or organisation to seek the individual's consent to the collection;	This recommendation is for an exception to UPP 2. It should be made clear that this exception would apply to the collection of all sensitive information, including health information. As we have suggested in relation to the health privacy regime, it is desirable to expressly distinguish between the health privacy regime, which applies to most uses of health information but not research, and the research regime which applies to all personal information including all sensitive information including the defined sub-set of health information.

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	(d) a Human Research Ethics Committee—constituted in accordance with, and acting in compliance with, the *National Statement on Ethical Conduct in Human Research* as in force from time to time—has reviewed the proposed activity and is satisfied that the public interest in the activity outweighs the public interest in maintaining the level of privacy protection provided by the *Privacy Act*; and (e) the information is collected in accordance with the Research Rules, to be issued by the Privacy Commissioner. Where an agency or organisation collects personal information about an individual under this exception, it must take reasonable steps to ensure that the information is not disclosed in a form that would identify the individual or from which the individual would be reasonably identifiable.	The word 'and' should be inserted at the end of (a) (b) and (b), to make it clearer that *all* of the conditions (a)-(e) must be satisfied (as in the current NPP 10.3). Relying on the use of 'all of the following conditions ..' in the preamble is not sufficient, as many of the other principles contain lists of alternate exceptions. The addition of 'unreasonable' as well as 'impracticable' in (c) is dangerous as it opens up the prospect of self-interested judgments by agencies and organisations which undermine the intended stringency of the test to be applied. To avoid this, it should be expressly provided that the Research Rules to be issued by the Privacy Commissioner must include rules concerning what may be considered 'unreasonable' for the purposes of (c). We accept that there may be a stronger case for an 'unreasonable' as well as an 'impracticable' test in relation to research uses than in relation to the collection, use and disclosure exceptions for health information (see separate submission above). This is not only because of the public interest in research but also because the proposed research exceptions have the additional safeguard of the requirement for "reasonable steps to ensure that the information is not disclosed in a form that would identify the individual or from which the individual would be reasonably identifiable." The ALRC proposal changes the test to be applied by Ethics Committees from 'substantially outweighs' to merely 'outweighs'. We are not persuaded by the case

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		for this change, which would significantly weaken the level of privacy protection afforded by the new Research Rules. The test should remain 'substantially outweighs'.
derogation from use and disclosure principle	**Recommendation 65–9** The research exception to the 'Use and Disclosure' principle should provide that an agency or organisation may use or disclose personal information where all of the following conditions are met: (a) the use or disclosure is necessary for research; (b) it is unreasonable or impracticable for the agency or organisation to seek the individual's consent to the use or disclosure; (c) a Human Research Ethics Committee—constituted in accordance with, and acting in compliance with, the *National Statement on Ethical Conduct in Human Research* as in force from time to time—has reviewed the proposed activity and is satisfied that the public interest in the activity outweighs the public interest in maintaining the level of privacy protection provided by the *Privacy Act*; (d) the information is used or disclosed in accordance with the Research Rules, to be issued by the Privacy Commissioner; and (e) in the case of disclosure—the agency or organisation reasonably believes that the recipient of the personal information will not disclose the information in a form that would identify the individual or from which the individual would be reasonably identifiable.	This recommendation is for an exception to UPP 5. The word 'and' should be inserted at the end of (a), (b) and (c), to make it clearer that *all* of the conditions (a)-(e) must be satisfied (as in the current NPP 10.3). Relying on the use of 'all of the following conditions ..' in the preamble is not sufficient, as many of the other principles contain lists of alternate exceptions. The addition of 'unreasonable' as well as 'impracticable' in (b) is dangerous as it opens up the prospect of self-interested judgments by agencies and organisations which undermine the intended stringency of the test to be applied. To avoid this, it should be expressly provided that the Research Rules to be issued by the Privacy Commissioner must include rules concerning what may be considered 'unreasonable' for the purposes of (b). We accept that there may be a stronger case for an 'unreasonable' as well as an 'impracticable' test in relation to research uses than in relation to the collection use and disclosure exceptions for health information (see separate submission above). This is not only because of the public interest in research but also because the proposed research exceptions have the additional safeguard of the requirement for "a

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		reasonable belief that the recipient will not disclose the information in a form that would identify the individual or from which the individual would be reasonably identifiable." The ALRC proposal changes the test to be applied by Ethics Committees from 'substantially outweighs' to merely 'outweighs'. We are not persuaded by the case for this change, which would significantly weaken the level of privacy protection afforded by the new Research Rules. The test should remain 'substantially outweighs'.
ethics committees	See Recommmendations for Research exceptions to UPPs 2 & 5, and Research Rules.	We understand that there may be practical difficulties in access to Human Research Ethics Committees by many researchers in areas other than universities and certain research institutes. The government needs to consider if it intends to require the setting up of ethics committees to service these other researchers – for instance those in agencies and NGOs, and to provide appropriate resources. Alternatively, a specialised unit could be established within the Privacy Commissioner's office, with appropriate skills, to perform this role.
66. Research: Databases and Data Linkage		
	Recommendation 66–1 The Privacy Commissioner should address the following matters in the Research Rules:	Support, subject to adequate consultation requirements, which should be modelled on Part VI (Public Interest

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	(a) in what circumstances and under what conditions it is appropriate to collect, use or disclose personal information without consent for inclusion in a database or register for research purposes; and (b) the fact that, where a database or register is established on the basis of Human Research Ethics Committee approval, that approval does not extend to future unspecified uses. Any future proposed use of the database or register for research would require separate review by a Human Research Ethics Committee.	Determinations), including public notice and hearings.
	Recommendation 66–2 Agencies or organisations developing systems or infrastructure to allow the linkage of personal information for research purposes should conduct a Privacy Impact Assessment to ensure that the privacy risks involved are assessed and adequately managed in the design and implementation of the project.	Support – this would help to address the concerns expressed below.
	Recommendation 66–3 The Research Rules, to be issued by the Privacy Commissioner, should address the circumstances in which, and the conditions under which, it is appropriate to collect, use or disclose personal information without consent in order to identify potential participants in research.	Support The ALRC appears to accept that sophisticated data linkage models provide sufficient privacy protection even where there is no permanent and irreversible de-identification. These arrangements, involving third party intermediaries, can offer a high level of privacy protection, and should be encouraged as a form of 'privacy enhancing technology'. We would be concerned however if there was any concession in the law that anything other than permanent and irreversible de-identification could take information outside the definition of 'personal information' and therefore outside the privacy

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		protection framework of the Privacy Act.