Alfred Health Ethics Newsletter

March – June 2014

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Changes to the Privacy Act

The Privacy Act (Cth) 1988 (the Act) was amended on 12 March 2014 and includes a set of 13 new privacy principles, called the Australian Privacy Principles (APPs), which have replaced the existing Information Privacy Principles (IPPs) and National Privacy Principles (NPPs).

The **APPs** set out requirements for the management of **personal information**, including the way it is collected, stored, used and disclosed.
"Personal information" is information about an identifiable individual, and includes sensitive information which includes **health information**.
A useful fact sheet about the APPs can be downloaded from the website of the Office of the Australian Information Commissioner.

The Act applies to Commonwealth and ACT government agencies, certain private sector organisations including private sector health service providers and private and ACT universities (APP entities). Thus pharmaceutical and device companies and other private organisations like Baker IDI and the Burnet Institute must comply with the Act. Whilst public hospitals and Victorian universities are not *directly* required to comply, researchers need to be aware (and meet the privacy standards) of the APPs if they seek personal/ sensitive /health information from APP entities.

Outlined below are selected APPs of relevance to research that involves APP entities. Most are also pertinent to the Participant Information and Consent Forms (PICFs):

APP 1 requires an APP entity to have a **privacy policy** in place that describes the management of personal information by that entity. For example the policy should detail how an individual may seek access and correction of personal information held by that entity. The policy needs to be available free of charge and in an appropriate form, e.g. on the entity's website or supplied if requested.

APP 5 deals with the collection of personal information. It also includes the requirement that the individual be made aware of an APP entity **disclosing** his/her **personal information to overseas recipients**. If practicable, the **countries** in which these recipients are located should be **specified**.
Further APP 5 requires that the individual be informed that the APP entity's privacy policy contains details of how the individual may **complain** about a breach of the APPs.

APP 8 deals with **cross-border data transfer**, for example the disclosure of personal information from the local sponsor (the APP entity) to the international sponsor. As per APP 8.1 an APP entity needs to take reasonable steps to "ensure that the overseas recipient does not breach the APPs". APP 8.2 lists a number of exceptions to APP 8.1 including where the APP entity reasonably believes that the overseas recipient is subject to privacy regulations similar to the APPs.
APP1 also does not apply if the individual consents to the cross-border disclosure after being expressly informed that the overseas recipients may not handle his/her information in a manner compliant with Australian privacy laws (subclause 8.1 of the APPs will not apply to that disclosure).

The various PICFs developed by the NHMRC and published by the Department of Health have been revised to include explanations of the relevant Commonwealth and Victorian laws.

In short wording needs to be included in the PICF to address the following:

- Specify the overseas country (ies) that the personal information is disclosed to and whether the overseas recipient(s) is/are compliant with the APPs (if not compliant refer to exceptions detailed in APP 8.2).
- The contact details of the person (e.g. Privacy Officer of the entity) in case the participant wants to lodge a complaint regarding a breach of the APPs or wishes to access/correct the information held by the entity about him/her.

Again investigator-initiated studies where the protocol belongs to either public hospitals (e.g. Alfred Health) or state universities (e.g. Monash University) are not APP entities. Instead these entities need to comply with the Health Records Act 2001 (Vic) with regards to the handling of health information and with the Information Privacy Act 2000 (Vic) with regards to the handling of personal information. It is worth noting that the Health Privacy Principles (HPPs) in the Health Records Act also require that individuals have the ability to access/correct their information (HPP6), and have similar requirements to the *Privacy Act* in relation to transborder data flow (HPP9). The Health Records Act also provides for complaints to be made to the Health Services Commissioner.

Common mistakes in Low Risk applications

- Section C 'Privacy' of the Low Risk Form:
  Checking the 'Non-identifiable' data box when you are collecting information from the medical records is incorrect.
  A person's **UR number** is considered **identifiable information** (as are name and DOB). Researchers need to explain how the identifiable data will be dealt with once the data has been collected. Non-identifiable data does not have any identifiers attached to it, while identifiers have been replaced by a code in coded/re-identifiable data.
- Section D 'Consent' of the form: If you are using identifiable data (e.g. use of previously collected data from the medical record) or re-identifiable information without patient consent, then either the shaded section may be appropriate or you will need to apply for a Waiver of Consent.

Please see the Low Risk Guide on our website as well as section 3.2 of the National Statement.

Reminders

a) Payment forms
Please remember to submit the Ethics & Research Governance payment form with each project and amendment application. Please refer to the fee schedule for more information. Since the fee schedule was introduced in August 2013, there have been a number of inquiries about whether or not a fee is applicable – mostly for projects that are investigator-initiated. We hope that the following information will provide further clarification.
Research initiated by staff from AMREP-affiliated institutions and applications from other external bodies contribute to a large proportion of the research applications, monitoring and amendments that are processed by the Office. In order to gain some contribution from institutions that use the Alfred Hospital EC and Office services, the fee for AMREP-affiliated institutions was introduced and other fees were adjusted accordingly. Please note that the Office of Ethics & Research Governance at Alfred Health is funded by the fees.
The intention is to apply the fees fairly and consistently. For investigator-initiated studies (without commercial support) the criterion is based upon the institution that is deemed to be the custodian of the protocol. Where this is a shared arrangement or where researchers have dual appointments, the fee is determined by the institution that is in receipt of funding. The fees are not based on the appointment of the Principal Investigator or other members of the research team.
Please contact Emily Bingle (9076 3619) if you have any questions.

b) Resource Centre Declarations
When completing an application to the Ethics Committee, please ensure that the signed Resource Centre Declarations include all of the services required from the relevant departments. When amending a project, ensure that new or revised Resource Centre Declarations are submitted with the amendment where applicable.
Please note that a Health Information Services (HIS) Declaration is required for all projects involving access to medical records for research purposes, regardless of whether the access is electronic only (no cost) or involves retrieval of hardcopies (charge).
Researchers using Alfred Pathology services are required to complete a Pathology Declaration even if the tests are part of standard clinical care. Please note that only tests additional to routine care will be costed.

c) When sending PICFs to Health Information Services (HIS) for scanning…..
- Please ensure that there is a patient label or at least the patient's name and UR number on the first page of the form.
- If scanning of unsigned participant information forms is required, please indicate accordingly.
- Please provide the details of the person responsible for sending the consent forms in case HIS have questions.

If you have any questions, contact Ms. Dial Gill (Service Manager, HIS) on ext 62540.

Cartoon © Don Mayne

d) Use of resources and hospital services
Please consider all resources to be used (e.g. staffing, data sources, diagnostic tests and consumables) and include these in your budget. Please also complete Resource Centre Declarations (RCDs) forms where hospital departments will be involved in providing services such as pathology and radiology. The declaration must state all tests to be performed (regardless of standard care or for research).
An itemised budget and fully signed RCDs need to be submitted with your full submission.

If stickers are to be placed on request slips or request slips have been generated for a research project, these must be used. This allows service providers to use the correct set-up (e.g. an imaging protocol) and to invoice for the service correctly.

The Research Review Committee: Interview with Professor Richard Gerraty

What made you decide to become an RRC and EC member in 2006?
I had just started at the Alfred and was working with Judy Frayne and she suggested it as a very good committee to join with interesting protocols to review and a very efficient structure with the research review committee looking at the drug and intervention studies ahead of the main meeting.

What do you enjoy most about working on the RRC?
I enjoy the content and the company, the quality of discussion, the fairness and insight of the reviewers and Colin Johnston's chairmanship which is both critical, but very tolerant. He has a vast experience and wide knowledge and we all benefit from that. I often think that it is the best committee I will ever be on.

After the positive – what do you find challenging about the RRC?
Four protocols to review when I have forgotten them till Sunday night, and working late I find that there is one I cannot work out what the primary endpoint actually is. And then there's the NEAF. I once raised a point about item 4.1.1.1.1.12 in the RRC, and the chairman thought I was joking.

Having been involved in ethics for some years now, what do you think has changed a lot with regards to ethics/research over time?
There is access to the low risk pathway, which has been a great development as it is so efficient. The professional secretariats have grown, and the diversity of people has improved the process I think.

You trained to become a Neurologist. Why did you choose this speciality?
It was probably a project on the eye in high school that got me interested, and then second year physiology at university and John Eccles book on neurophysiology, and the Alfred neurosurgeon, Keith Bradley's neuroanatomy lectures.

You are involved in a lot of stroke research. Being on the receiving end of ethics feedback at times, how do you think this influences your work on the Committee?

One of the most important things I have learnt on the receiving end is consideration of the risk of routine tests. Warning patients volunteering to have an MRI that something significant might be found and that this needs to be considered in the adverse effects of study participation.

Which issues in stroke management do you hope can be overcome in the near future?
Some doctors in Australia maintain a position that thrombolysis for stroke is unproven. This is surprising, and has a number of causes. I think that more medical student and new graduate participation in research will help the next generation of doctors see a new treatment when it arrives, just as they should of course be sceptical about those for which the evidence is poor.

You were born in Great Britain. What made you come down under?
My parents were both from Melbourne and my mother eventually longed for a flat horizon and a dead gum tree. I was 5 when we came here.

What is your favourite place in Australia and Melbourne and why?
I love going to Lorne each year, the milder temperatures, the moist air, the gentle surf, and the rain forest. It is unique. In Melbourne my favourite spot is a bend in the river near us now being overbuilt with apartments unfortunately.

Which projects outside your area of expertise do you enjoy reviewing?
I like the surgical studies. I think physicians are frustrated surgeons.

You have an interest in photography. What do you like to take pictures of? Just private or do you publish them (internet, photo competitions etc.)?
I like walking with a camera, looking at the light and familiar objects, even if I don't take a single photo. I take the same walk around Richmond at lunchtime when I can, and the same route around home late on a Sunday afternoon. I will usually find something interesting and surprising and very often not repeatable. I am a member of a small photographic group that meets monthly.

Education sessions for Alfred Health/ AMREP researchers

Information session: The Victorian streamlined review process and the National Mutual Acceptance (NMA) streamlined review process for Clinical Trials
When: 05August 2014, 12.30 –1.15pm
Where: AMREP Education Centre, Classroom 2

Workshop: PICFs for Victorian streamlined and NMA streamlined review studies
When: 19 August 2014, 12.30-1.15pm
Where: Ethics & Research Governance Office (small group session)

The sessions will be run by Angela Henjak. For inquiries and RSVP email e.bingle@alfred.org.au