Alfred Health Ethics Newsletter

March – April 2015

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Help Us Help You

Documents received by the Ethics Office often contain errors that it seems could have readily been avoided. Admittedly it is easier to look for mistakes than to complete an ethics application yourself. In an effort to help avoid delays occurring through the submission of incorrect or late documents, we have composed an article on strategies to deal with time pressure and to employ effective checks and balances, which we hope you find useful as well as entertaining.

Time management
Write to-do-lists for tasks that need to be completed, short-term and long-term. Noting the due date in your calendar as well as scheduling dedicated time for a task can assist in avoiding time pressure when rushing through due tasks last minute – a recipe for errors.
For example entering the submission deadlines and the dates when responses are due in your calendar may help in getting organised with new project submissions and allowing for ample time to prepare these thoroughly. The deadlines for project registration and full submission are available on our website. The responses for the EC meeting are due the Wednesday in the week before the EC meeting.

Checklists
It might also be helpful to develop a checklist for common tasks and highlight potential sources for errors. For example, when submitting an amendment application, a checklist listing forms to submit/upload might look as follows:

- Amendment form, Amendment fee payment form
- Changes to staff: Change to research personnel form
- Revised IB: IB form
- DSUR: DSUR form

Prompts for common scenarios may be:

- Change of protocol title? Submit revised CTN, indemnity and amendment to the agreement
- Addition of new staff? Submit CTRP form and current CV (if not done so in last 2 years)
- Protocol/IB changes? Submit 'Summary of changes' and tracked version of the protocol/IB

Updates to…

a) AMENDMENT SUBMISSIONS

For projects considered at 2014 Ethics Committee meetings and onwards:
Please submit your amendment, change to research personnel, revised IB and DSUR via our web-based ethics application management system ERA. Please refer to the ERA page for more information.
For projects considered at Ethics Committee meetings prior to 2014:
Please submit the documents stated above to research@alfred.org.au.

b) WEBSITE

The Legal page has been updated to include the following:

- Research Collaboration Agreement, suitable for non-clinical trials
- Checklists for the initial agreement and indemnities as well as for amendments to the agreement
- Amendments or addenda to agreements for instances where revisions to the initial agreement become necessary. Different templates for different types of studies are available. Sponsors may have their own template.

c) DOCUMENTS

- **Research Agreement Guideline**
  The intent of this guideline is to set out the requirements and procedures for the approval, signing, database entry and storage of all Alfred Health Research Agreements.

- **Radiation**
  The 'Medical Physicist Request Form' has been updated. Please include the completed form together with all other documents required to obtain a Medical Physicist Report for studies involving either diagnostic or therapeutic ionising radiation, prior to the project registration date to allow for the report to be available for project submission.

- **Resource Centre Declaration**
  If using The Baker IDI's imaging services please send the completed 'Declaration of Imaging Resources' to lisa.keam@bakeridi.edu.au.

Check your work
Double-check your work. The information provided in the application should be consistent. While it might be tempting to have templates (e.g. for the NEAF or VSM), these present a common source of errors. Better start from scratch when completing the application documents and save a set of common responses separately.
Ask a colleague to proofread your work. A buddy system might be an option, where you and a colleague take turns in proofreading each other's documents.
This would be particularly useful for important documents like the PICF. It reflects badly on the researcher, department and the whole organisation if documents going out to participants are full of mistakes.

Concentration
Juggling too many tasks at once that require your full attention may also lead to mistakes. Prioritising might be the way to go when trying to complete multiple tasks. A common suggestion is to alternate between easy or unfulfilling tasks and tedious or exciting ones to keep you motivated and focused. Avoid distractions like phone calls, emails and colleagues interrupting, if possible. An organised workspace helps as well. When your attention drifts, take breaks to help the mind to focus.

While this might seem trivial to many, a lack of attention to detail often results in a delay of getting a study approved/authorised. Submitting the wrong documents/old versions of documents or not responding to all queries raised contribute to approval/authorisation being delayed. To strive for the common goal of getting applications approved and authorised expeditiously, the Office would greatly appreciate if researchers took a bit more ownership and pride in the documents they submit.

We have created a list of things that frustrate the Office staff and called it the 'pet horse' list.
We are not immune to lapses – 'pet horse' is a combination of 'pet hate' and 'hobby horse', created by accident by an unnamed 'foreigner' in the office.

The official 'pet horse' list:

Submission of documents that have been superseded
Please use current templates/forms available on our website.

Deletion of questions in application forms
Researchers sometimes delete questions that they feel are not applicable to their research. This delays the reviews, as one has to establish which questions have been deleted and whether they might actually be relevant to the project. In a worst case scenario, relevant aspects of a study are not considered because the question that would have highlighted the issue has been deleted. This might create problems down the track. Instead of deleting questions please state N/A.

Submission of clean versions when revising documents
Please submit amended documents using the 'tracked change' format to facilitate their review.

Failure to update the version number and date when revising documents
In the name of 'version control' please assign the subsequent version number and a current date to an amended document. Do not forget to track the changes to version number/date, so that it can be easily ascertained whether you worked off the latest approved version of a document.

That leads to another 'pet horse' – the use of a superseded version of a document as a template to work off when revising the document
Researchers should have a filing system in place that enables them to quickly determine the latest approved version of a document. For studies submitted via ERA, you can find the latest approved version of each document type in the 'Files' tab. Previous versions can be accessed by clicking on the number stated in the 'Revision' column.

Passing on documents from the sponsor without checking them first
Documents containing errors will result in delays. We acknowledge that we usually do not have time to straight away look through documents sent to us, but this delay will be lengthened if we have to point out the errors which then subsequently have to be addressed and approved by the sponsor before the application can be sent out for review. This can be avoided if researchers act as gatekeepers and check for mistakes and missing documentation before forwarding the documents to us.

Failure to check legal documents
Errors in legal documents also amplify any delay in approval, as these are often submitted later in the review process. For example an invalid insurance certificate, usually only detected when the first review has taken place, may delay project approval when a new certificate needs to be reissued. Some errors like an incorrect protocol title are easily avoided. Checklists are available to assist researchers in completing agreements and indemnities correctly.

Submitting scanned documents
The submission of scanned files other than signatures is discouraged, as it impairs the review of an ethics application, e.g. when searching for a term in a document.

Labelling data or samples as 'de-identified'
The use of the term 'de-identified' is discouraged, as its meaning is unclear. Data/samples are either individually identifiable, re-identifiable/coded or non-identifiable (refer to section 3.2 of the National Statement for more information).

Incorrect declaration of access to identifiable data (Q 3.2 in the VSM; Q1.25 in Module One)
Medical records are considered individually identifiable data. Therefore the question 'Does the project involve the collection, use or disclosure of individually identifiable or re-identifiable information from sources other than the individual to whom the information relates?' should be answered with 'yes' if medical records are accessed. Please note that access to identifiable records for the purpose of extracting non-identifiable data constitutes 'use' and 'disclosure' of identifiable data even if such data will not be 'collected'. If obtaining participants consent to access their medical records the follow-on question 'Does the project involve the collection, use or disclosure of information without the consent of the individual to whom the information relates (or their legal guardian)?' can then be answered with 'no'.

But it is not all doom and gloom. Lapses in attention to detail provide a great source of entertainment for the Office at times:

- "…may be located in your, and country or other countries that are outside of your country"
- "Absintence as part of your normal lifestyle is also acceptable."
- "…is incredibility busy…"
- "PI is associated with discomfort and pain and can lead to prolonged hospitalization"
- "This research project will be monitored by a Steering Committee compromising a Haematologist, Dieticians and Nurses…"

If you have any strategies/tips on how to avoid errors that you found useful and wish to share with other researchers, please email these to Katja. We will include a selection in the next newsletter. Thank you.

Education sessions for Alfred Health/ AMREP researchers

The Office is offering training for researchers on different topics. Please see the table below for more information and register your interest by contacting Emily (9076 3619).

Placebo to be included in CTN

As advised by the Therapeutic Goods Administration (TGA): If a study involves the administration of a placebo, even if the study drug is TGA-approved and will be used for a TGA-approved indication, a Clinical Trial Notification (CTN) form must be submitted just for the placebo. The reason being is that placebos are not included on the Australian Register of Therapeutic Goods (ARTG). Therefore an exemption must be in place for the goods to be lawfully supplied for human use. The relevant exemption for goods used in clinical trials is provided by submitting the CTN form.

Eligibility for Expanded Scope of SERP

The scope for the types of research eligible for the Victorian Streamlined Ethical Review Process (SERP) has expanded to health and medical research. However, it will be a requirement for all researchers intending to submit a SERP application that they have either already prepared one previously or have attended a streamlined process training session (see below). We are also in the process of modifying application forms to capture information for non-clinical trials. Therefore, please contact the Office prior to submitting or being included in a SERP application.

Movie Review for 'Cordon' by Emily

Those with an interest in infectious diseases and how to control a deadly viral outbreak shouldn't miss ***Cordon***. On second thoughts, it is probably a better depiction of how not to manage a viral outbreak.

The setting for the series is Antwerp, one of Europe's largest shipping ports, and it is actually shipping containers that are used to seal off the area of the city at the epicentre of the viral infection.

It quickly becomes apparent that managing the outbreak is going to take longer than a few days and the cordoned area essentially becomes lawless, with a criminal network taking over the distribution of food and a nasty gang controlling the streets.

There are some main characters within the cordon, including the head of the infectious disease research institute, a police officer and the girlfriend of the police commissioner.

Lex, the lonely police commissioner, is on the outside and he is responsible for the security of the cordon. He soon realises that the story about the source of the outbreak doesn't add up and hooks up with a rogue journalist to investigate further. This upsets the Thatcher-like Lommers who is suddenly in charge of everything and seems to have her own agenda.

The show is dark, depressing and at times violent. The depiction of the unlucky people who become infected is pretty awful so consider this a warning.

So why watch something so bleak? There are 10 episodes in the first series and I found it interesting to watch the change in morals and behaviour, both from those on the inside and those on the outside of the cordon. The series certainly raises some ethical questions, ranging from who should have access to a possible treatment through to the role of the media in providing information to the general public.

Title	Date	Time	Location
Legal and Regulatory Documents	22/Apr/2015	10:30AM - 11:15AM	AMREP Education Centre Classroom 3
Low risk Applications or Reviewing Site Applications (TBC)	20/May/2015	10:30AM - 11:15AM	AMREP Education Centre Classroom 1
PICFs for streamlining or Accepting Site Applications (TBC)	18/Jun/2015	10:30AM - 11:15AM	AMREP Education Centre Classroom 3
Registries	15/Jul/2015	10:30AM -11:15AM	AMREP Education Centre Classroom 2
Streamlined Ethics Review Process – Reviewing Site Applications	19/Aug/2015	10:30AM - 11:15AM	AMREP Education Centre Classroom 1
Streamlined Ethics Review Process – Accepting Site Applications	17/Sep/2015	10:30AM - 11:15AM	AMREP Education Centre Classroom 3
Legal and Regulatory Documents	14/Oct/2015	10:30AM - 11:15AM	AMREP Education Centre Classroom 3

The Research Review Committee: Interview with Professor Leon Bach

You have been an RRC member since January 2013. Has being on the Committee influenced your work as a researcher?
It has certainly made me think more about the ethical implications of my work and fill out the forms more carefully!

What do you like about the work on the Committee? If you wanted to convince someone to join the RRC what would you tell them?
It's a great opportunity to find out about the breadth and quality of the research being performed here. The interaction with like-minded colleagues is also great fun and some of the debates are very stimulating. Finally, it's an opportunity to give something back to the research community here.

You excelled in Physics and Applied Mathematics in High School. Did you contemplate a career in science? What made you decide to study medicine?
I'm glad someone has read my CV in such great detail! I was always interested in maths but decided on medicine because of the broad range of opportunities it provided to develop a multifaceted career.

You have an interest in protein-protein interaction. Can you tell our readers about a protein-protein interaction that you find fascinating?
Not without sounding like a total nerd!

Last year 'The high burden of inpatient diabetes mellitus – The Melbourne Public Hospitals Diabetes Inpatient Audit', published in the Medical Journal of Australia, revealed that, while the prevalence of diabetes in the adult community is believed to be between 5 and 10 per cent, one in four in-patients in Melbourne hospitals are affected by diabetes. Are any follow-up studies planned? What changes would you like to see flowing on from this study? Were there any unexpected findings?
We're now looking to see whether we can identify subpopulations of hospital inpatients that are at especially high risk of diabetes, and also plan to examine the consequences of diabetes on outcomes. Ideally, I think that a broader Australia-wide survey to include regional centres would be very useful. However, the ultimate aim of the study was to make the community aware of the prevalence of diabetes with a view to optimising its detection and management.

You are Deputy Director of the Department of Endocrinology and Diabetes at the Alfred and Head of the Molecular Endocrinology Laboratory at Monash University. Do you see a translation from your team's work in the lab into the clinic?
My lab work is very basic so there have not been any direct translations yet. However, I have been involved in some clinical studies related to diabetic complications that derive from work closely related to mine.

When you review ethics applications what is the most common error you come across? What annoys you most?
I am most annoyed by lazy applications that are 'cut and pasted' without any attention to detail so that different parts contradict each other. Another common error is lay statements written in technical language e.g. in the PICF.

You completed post-doctoral studies at the National Institutes of Health (Bethesda, MD) and took a sabbatical at the University of Cambridge. How does the research culture overseas compare to the research climate in Australia?
I have been privileged to work in two of the best research organisations in the world. The most striking difference from here is the availability of resources which allow research of the highest quality to be performed. Having said that, the calibre of Australian researchers is highly regarded in both places.

You are involved in student and junior medical staff education. Do you believe researchers are taught adequately about research ethics? Where do you think education could be improved?
Ethics underpins all of clinical practice and not just research, and students and junior doctors are increasingly made aware of this. It is difficult to see how direct education in ethics could be increased given the huge amount of information that students already need to integrate. However, mentoring is very important and it's always a pleasure to see a junior colleague find his or her feet in the research world, including an appreciation of ethical issues.

Intensive Research Ethics Course

The course is organised by the Centre for Ethics in Medicine and Society (Monash University) and the Centre for Values, Ethics and the Law in Medicine (University of Sydney). It takes place Sunday 31 May to Thursday 4 June 2015 at Bowral, NSW. You can find further information here. The early bird discount finishes 30 April.

Happy Easter