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What do we find when we audit?

We are continually impressed by the high standards of important, ground-breaking research being conducted across Alfred Health. We regularly audit studies approved by the Ethics Committee to provide assistance with ethical and legal issues and to check that standards are consistently maintained. The following tips relate to areas commonly found to be in need of improvement:

- Conduct timely and thorough handovers for new research staff (especially rotational staff). Don't assume the next person will have the same level of experience and knowledge as you. The study files should be kept in order so that if anything happens to you, someone else could easily take over your role. The [self-audit](#) is designed to remind you of your obligations.
- Provide all staff with adequate training.
- Know your protocol inside out: don't recruit outside the inclusion criteria; don't add in extra procedures; do collect the information required. If the protocol is not followed, the ramifications can be serious, affecting patient safety, insurance and more.
- Use the most recently approved version of the Participant Information & Consent Form (PICF).
- Try to make a reasonable estimate of how long the research will take to complete. More than 75% of researchers significantly underestimate timelines.
- Some consent forms have been found to contain illegible names, missing participant signatures, researcher and witness signatures and dates. The PICF is a key research document and verifies that consent has been obtained. Incomplete PICFs can compromise the integrity of the research.
- Keep PICFs in the study files (ie keep the Information Sheet and signed Consent Form together). A copy should go in the patient's medical record.
- If seeking consent from the Person Responsible or using Procedural Authorisation, make sure you carry out and clearly document the follow-up consent procedures.
- Make sure the person/s gaining consent and/or explaining the study is/are the same as those stated in the ethics application.
- Check that you understand SAE definitions and record and report these if they occur.
- Keep a log of SAEs if you are a coordinating site so you can keep track of them across sites.
- Periodically audit your own data to check for accuracy.
- Store and transfer data in the manner you have specified in the ethics application.
- Inform us of any changes to research personnel as soon as possible.

If you have any enquiries regarding research governance and your obligations, contact [Nicole Rosenow](#).

Importing medical devices

New advice from the TGA

Please be aware that medical devices to be used in clinical trials, including diagnostic devices such as ECG machines that have been imported into Australia (by anyone other than a TGA-registered local supplier) need to be separately registered with the TGA, even if the device is listed on the ARTG. The process is simply to include the device(s) in the ethics application (Module 2 or VSM) and CTN form and incorporate specific wording in the PICF, which the Ethics Office will provide. Using a local supplier's ARTG from the TGA website is not appropriate unless you have written permission from them to do so.

The Biomedical Engineering Department has prepared an [information sheet](#), available on the Alfred Intranet, to clarify the process.

Please contact [Jono Nevile](#), Biomedical Engineering for further clarification.

New legal documents for devices

CTRA, Indemnity, Guidelines...

A Research Agreement template for trials involving devices has been developed by the Medical Technology Association of Australia (MTAA), the VMIA, NSW Health and QLD Health. The [Clinical Investigation Research Agreement](#) (CIRA) is to be used by Victorian Public hospitals when they are engaged by a device company to conduct a human trial involving their product. This Agreement has been developed specifically to address the requirements that attach to a device trial which otherwise could not be accommodated by the other CTRAs currently in place. The CIRA has adopted the same format as existing CTRAs, except for industry specific wording.

THE CIRA is to be used in conjunction with the [MTAA Standard Indemnity Form for a Clinical Investigation](#). There is also the [MTAA Standard Indemnity Form for a Clinical Investigation for HREC review only](#).

These indemnities also have specific [MTAA Compensation Guidelines](#).

There will also be specific “Compensation” wording in the PICF for device trials. The wording will be available in the PICF template shortly.

For further information, visit our [website](#) or contact [Angela Henjak](#).

Changes to Medical Physicist Reporting

The Victorian Department of Health has produced new guidelines and revised risk statements for Medical Physicists to use when issuing advice on radiation risk to be included in PICFs.

The changes mean that:

- Researchers will need to provide the **median life expectancy** of their participant group. This is in addition to checking the yes/no boxes on life expectancy of less than 5 years in the Module 4. The median life expectancy is to be supplied on the new Medical Physicist Request Form.
- The risk wording to be inserted into the PICF (when advised by the Medical Physicist) has been changed:
 - The comparator sentence used to describe the radiation dose in lay terms has been removed. Researchers are encouraged to discuss the risks with potential participants to ensure they understand the risks.

Reminder: Submitting PDFs to Ethics

Please send us your Progress reports and SAEs in **Word** format wherever possible. This allows us to easily acknowledge them, and cut and paste information into our databases.

However, IBs and protocols are **preferable in PDF format** as they are easier to navigate this way.

- The ratio of risk from harm of cancer has changed from that of fatal cancer to that of inducing cancer. This means that the risk of harm ratio will be higher. Again, researchers are encouraged to discuss the risks with participants.
- Risk wording will be required regardless of the life expectancy of participants where the radiation exposure is additional to standard care. Where participants do have a life expectancy significantly less than 5 years, the wording about risks of inducing cancer will not be included, but the magnitude of the dose will now be stated.

The new Medical Physicist Request Form to accompany these changes is available from the [Ethics website](#). All changes are effective immediately.

PICF contact details

One important purpose of a Participant Information and Consent Form (PICF) is to enable participants to easily contact the researchers.

The Ethics Office regularly receives calls from research participants seeking to make appointments or change arrangements. Sometimes people are confused about which number to ring; more often, they ring the ‘complaints’ number as a last resort after trying the researcher’s number to no avail. Please ensure that the contact number you provide will be attended, either by the researcher/research coordinator or by someone who can take a message. The general switchboard number should be avoided and a direct number and/or mobile phone number provided. Please also clearly distinguish in your PICF between the number for information/appointments and the number for complaints.

The Ethics Office has moved...

You can now find us in our new home, Ground Floor, Linay Pavilion, entrance opposite the bike sheds. All our contact details remain the same.

