**Electronic signatures on ethics documents via Australia Ethics Review Manager system**

The key question for public hospitals is whether or not the receipt of electronically signed declarations and other documentation submitted via the Ethics Review Manager (ERM) (**Website**) research system at <https://au.forms.ethicalreviewmanager.com/Account/Login> is acceptable from a risk perspective.

A hospital's risk assessment should take into account the features of the electronic signature method, and the risks arising for the hospital if the signature is not valid. In particular, hospitals should have regard to the following principles (which are taken from the Australian laws regarding electronic signatures generally):

* *identification* – a method is used to identify the person using the signature and to indicate the person’s approval of the information communicated;
* *reliability* – having regard to the relevant circumstances at the time the electronic signature method was used, the method was as reliable as appropriate for the purposes for which the information was communicated; and
* *consent* – the person to whom the signature is required to be given consents to that requirement being met by way of the relevant electronic method.

In order to assist hospitals in making an assessment as to their use and acceptance of electronic signatures, some observations are set out below as to how the above principles may apply to electronic signatures on the Website.

1. *Identification*

According to the Website, in order to electronically sign a declaration via the Website, a username and password as well as a job title/post, position and email address must be entered. The entering of such information is a particular deliberate act and requires knowledge of certain identifying information. This may assist public hospitals to be satisfied that the person who has electronically signed a declaration has been appropriately identified and has indicated their endorsement of the information that they are required to declare.

1. *Reliability*

The fact that individuals who electronically sign a declaration must provide a number of items of personal information, and must have an account with access credentials to use the Website, also supports the electronic signature method being reliable.

Public hospitals should also consider whether they have appropriate processes in place to ensure that individuals who may submit declarations through the Website keep their access credentials appropriately protected from misuse (and do the same for their email addresses, which may be used to retrieve passwords for the Website via the forgotten password mechanism). The user is expressly instructed to keep their passwords confidential.

1. *Consent*

It should be verified that the body who is to receive the electronically signed document (which we understand is generally a hospital's HREC) is amenable to the receipt of electronic signatures, in order to satisfy the requirement for consent.

In addition, a hospital should take into account:

* any features of the Website that permit production of copies of declarations that have been signed, and records about the timing and manner of their signing, so that they have comfort about electronically signed documentation being able to be used in any litigation concerning the relevant research, if required. The maintenance of records as required under sections 5.2.24 to 5.2.26 of the *National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015)* may also assist hospitals to be satisfied about this; and
* any specific laws or contractual obligations that may apply to the conduct of any particular research that is the subject of documentation submitted via the Website, and whether those laws or contracts impose any requirements regarding the form and signature of relevant documentation.