Getting ready for Health & Medical Ethics in ERM

One Form for All Human Research

- Health and Medical Researchers will now be using Ethical Review Manager (ERM) to complete and submit the Human Research Ethics Application (HREA) for all ethics applications, except for Prior Approval. Entry Points -

1. Human Research Ethics Application (HREA)
2. Prior Approval Application

If you cannot meet 31 January deadline for lodging submissions via the current process, it is highly recommended you go to https://hrea.gov.au/ and start using the HREA now!

Serious Adverse Events & Protocol Deviations

- Health and Medical Researchers will now be able to report Serious Adverse Events and Protocol Deviations in ERM. These are sub forms which can be created by clicking on "Create Sub Form" in the navigation panel.

Amendments and Change of Chief Investigator Form

- There will no longer be an Amendment or Change of Chief Investigator form, as an amendment section will now be available within the Human Research Ethics Application.

Clinical Trial Researchers

New Annual Safety Report & Significant Safety Issue Forms

- Clinical Trial Researchers operating under the NHMRC - Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods (2016), will now be able to complete and submit an Annual Safety Report form and a Significant Safety Issue Notification form within ERM.
External Researchers
- If a Researcher is external to the University, an account will need to be created. Details around this process will be announced soon.

Process for Amendments
- Researchers will be required to complete an Amendment Request sub form to unlock their application to make changes. This is because applications will be locked at the time of approval to maintain their integrity. It is important to remember this cannot be actioned by the Research Integrity and Ethics Unit outside of business hours (Monday to Friday 9am - 5pm.) After an amendment request has been actioned, a confirmation e-mail will be received.

Functionality
- Researchers will be able to attach pictures (flow charts and diagrams) to support their ethics applications within ERM.

Signatory Requirements
- The Chief Investigator is responsible for the project and is the only person who will need to sign-off on the application. This is because the University is putting trust back into the Research Community.

Support
E-mail online.ethics@utas.edu.au or Visit - www.utas.edu.au/research-admin/research-integrity-and-ethics-unit-rieu/erm