AHREC Ethics Process Key Changes

Key messages by change impact

July 2019

Summary

This document highlights key changes that impact:

- Auckland Health Research Ethics Committee (AHREC) ethics applicants both from the University and from Auckland District Health Board (ADHB)
- Faculty/LSRI sign-off staff i.e. Academics Heads
- AHREC committee members
- Faculty/LSRI ethics advisors
- Faculty/LSRI Māori advisors
- Faculty and Institute Research Service Teams (FIRST)
- Ethics and Integrity Team

This document provides key messages and any associated further information to support understanding of the changes applicable to the introduction of Infonetica Ethics Review Manager (Ethics RM) to manage the AHREC ethics application process. The document is designed to provide a quick reference guide for each category of change:

- AHREC Eligibility Criteria Changes

- AHREC Application Form Changes

- System / Technology Changes

- Reporting Changes

- Process Changes

Where supporting information is available to further explain the change this information has been linked under the 'Further Information' column.

Key messages by change impact

AHREC Eligibility Criteria Changes

	Key Changes	Key Messages	Further Information
1.	**AHREC eligibility criteria expanded to include Counties Manukau District Health Board**	The AHREC eligibility criteria expanded to include Counties Manukau District Health Board (CMDHB) – • The scope of the AHREC ethics committee is expanding to provide ethical oversight and approval of clinical research (which is not eligible for review by a Health and Disability Ethics Committee (HDEC)), carried out by staff and students of the University of Auckland, the Auckland District Health Board **and Counties Manukau District Health Board**. • With this change, AHREC will also provide locality governance approval for studies that require CMDHB locality governance approval as long as the study does not require CMDHB Research Review Committee assessment (e.g. does not require a CMDHB budget)	

AHREC Application Form Changes

	Key Changes	Key Messages	Further Information
2.	**Responsiveness to Māori questions**	• Following the National Ethics Advisory Committee (NEAC) consultation in 2018 of the draft ethics standards for Health and Disability Ethics Committees (HDECs), Dr Helen Wihongi from Auckland/Waitamata District Health Boards developed a series of responsiveness to Māori questions • These questions have been included in the revised AHREC application form	

System / Technology Changes

	Key Changes	Key Messages	Further Information
3.	**Access to applications**	• Research Service Managers (RSM) in each Faculty/LSRI will be able to view the status and other key information of all applications for all of the University • Researchers/applicants will be able to see their own applications only • PHD, Masters and Honours students will have access to complete an application in Ethics RM	
4.	**Access to Ethics RM when off campus**	• Ethics RM can be accessed from anywhere via a web browser and using your University user name and password i.e. mdud399 and password1 • You do not need to use VPN when accessing Ethics RM off campus	
5.	**Access to Ethics RM for non-University staff**	• Persons requiring access to Ethics RM who are not employed by the University i.e. ADHB employees, committee reviewers etc. will need to apply for a University UPI and password	Will be provided in 'Ethics RM - On-boarding for external users' Quick Reference Guide
6.	**Auto-save of application data**	• The Ethics RM System will auto-save when moving between the application pages or sections using the 'Next' button • The AHREC application form has been designed with small sections and pages to ensure minimal data loss in case of time out on a particular page • A 'Save' button is also available to save your application as you complete it	
7.	**Spell check**	• There is a browser based spellcheck used in the application form	
8.	**Size of text fields**	• Ethics RM text fields have no size limit	

	Key Changes	Key Messages	Further Information
		• The text fields also expand as required and accept scientific symbols	
9.	**System notifications**	• A number of system notifications will be sent from Ethics RM when an application reaches a number of different stages	Will be provided in 'Ethics RM - System Notification Matrix'
10.	**Attachments to application form**	• Document attachments are associated with individual questions rather than the whole application form • The system will remind an applicant on submission to include an attachment if a document is a mandatory requirement for a question	
11.	**Transfer application to another person**	• Ownership of an application can be transferred by the current owner (Principal Investigator or Academic Supervisor) when e.g. the current owner leaves the University	Will be provided in 'Ethics RM - Transfer Application' Quick Reference Guide

Reporting Changes

	Key Changes	Key Messages	Further Information
12.	**Ethics RM Dashboard**	• Summary information is provided to all users via a home page Dashboard • Information from this Dashboard can be exported to excel for further manipulation or sharing	Will be provided in 'Ethics RM - Dashboard Overview' Quick Reference Guide
13.	**Adhoc Reports**	• The Ethics and Integrity team members have the ability to extract a CSV data file of all information available in Ethics RM • This information can then be further manipulated and shared • Other than the information available on the Dashboard, applicants and non-admin users do not have the ability to run reports	To request information / a report please email humanethics@auckland.ac.nz

Process Changes

	Key Changes	Key Messages	Further Information
14.	**AHREC manual process now systemised**	• From mid-August, the current PDF submission process for AHREC ethics applications will be retired and applicants will need to submit and obtain sign off for their AHREC application using Ethics RM	
15.	**PHD, Masters and Honours student application process**	• All students (PHD, Masters **and Honours Students**) will now be able to complete their AHREC ethics applications in the system. • The academic supervisor or principal investigator (PI) **must first** create a 'shell' of the application (completing minimal details - short and full project title and principal investigator / supervisor name) and share the application with the student for completion. (This is necessary because the person who initiates the form in Ethics RM is the form owner and controls who can access and submit the form) • Once the student has completed the application in Ethics RM they ~~should~~ must then request their academic supervisor or PI to review and submit their application for Academic Head sign-off • A Word version of the AHREC application form will still be available for those who wish to continue providing feedback on a student's application using tracked changes. Once the Word version application is finalised the student can copy the content into the online Ethics RM for and request submission by their academic supervisor or PI as per detailed above. (Ethics RM enables a PI or supervisor to insert review comments against the various sections of an application but these cannot be marked up with track changes)	Will be provided in 'Ethics RM - Completing an Application - Student' Quick Reference Guide
16.	**Peer Review of Applications**	• Peer review of applications can now be undertaken/managed inside of the Ethics RM system	Will be provided in 'Ethics RM - Commenting on an

	Key Changes	Key Messages	Further Information
		• Review comments from peer review are visible in system • Multiple reviewers can review and make amendments / comments at the same time • Comments from peer review are not retained once the application is submitted • A version of the application with the peer review comments available is, however, retained in the application version history	application' Quick Reference Guide
17.	**Committee Review of applications**	• All application reviews will be completed within Ethics RM - review of applications outside of the system will not be permitted • All applications, attachments and reviewer comments will be accessible directly from Ethics RM - reviewers will no longer need to go to the SharePoint document repository to access this information • The Ethics and Integrity Team will no longer need to create a PDF for each application that includes the application, the attachments and the reviewer comments	
18.	**Request for Academic Head sign-off**	• Your HoD (or delegate) must approve your AHREC application via Ethics RM before it is submitted to the Ethics and Integrity team for committee review • Applicants will need to add the name of their Academic Head (or delegated sign-off) once the application is ready for submission • If you are unsure who your HoD is please consult the University Directory, or ask your Faculty/LSRI Ethics Advisor or your FIRST representative • Once signed-off, the application will automatically be sent on to the Ethics and Integrity team and a notification will be sent to the applicant	

	Key Changes	Key Messages	Further Information
19.	**Amendment requests**	For a period of time, amendments to an approved AHREC ethics application will be managed in two ways, depending on how the initial application was processed. • If the initial application was previously submitted by email (prior to Ethics RM being implemented) the amendment request should be emailed as a PDF to ahrec@auckland.ac.nz using the current amendment request form (see below). • If the initial application was submitted using Ethics RM, any amendment request should be initiated through the Ethics RM system.	