Western Health

Ethics Review Manager (ERM) - WH Post Authorisation Submissions Guide

Please see below for a brief outline of the ERM Post Approval/Authorisation submission process. To submit Post Approval/Authorisation forms, you will need to log in to Ethics Review Manager (ERM). For further information regarding ERM, please see the Applicant User guide, available on the Department of Health website here.

For technical assistance with ERM please contact helpdesk@infonetica.net. For general queries regarding the post authorisation submission process and Western Health Site Specific requirements; please contact us on amendments@wh.org.au or refer to relevant sections on our website for details on additional requirements.

ERM Post Authorisation Submission Process (WH Site)

1. Log into your ERM Account.
2. In your Work Area, select your Project.
3. Under the Project Tree click on "Site Specific Assessment (SSA) Vic – Western Health".
4. On the left hand side under the 'Actions' Panel click on the 'Create Sub Form' button.
5. Select the desired form (e.g. Site Governance Amendment Request, Site Progress Report).
6. Under the 'Navigation' tab click on 'Information' under the heading 'Questions' in the middle of the page (you may have to scroll down the page).
7. Answer the questions accordingly. Click on 'Next' or 'Previous' button on 'Actions' panel to navigate through the form.
8. Upload all supporting documents with your SSA Sub-Form.

Please Note: You will need to upload a copy of the reviewing Human Research Ethics Committee (HREC) Approval Letter/Email, all applicable documents listed on the HREC approval and other WH Site Specific documents as required.

9. Upon completion, please provide signature of the Principal Investigator (PI) as below:
    1) Electronic Signature
        I. If you are the PI, select "sign". Enter your ERM login details and select "sign" again.
        II. Select "Request Signature" if you are not the project PI. Enter the PI's email address and select "Request".
        III. When the form has been signed by the PI, proceed to submit your form.
    2) Wet Ink Signature
        I. Print the form to obtain wet-ink signature from the PI.
        II. Upload the signed copy of the form to the application on ERM.

Please Note: When signatures are requested, the form will be locked to prevent further editing. If you unlock/recall your form, all signatures will be lost.

10. To submit your form, click on 'Submit' button on the left-hand side under the 'Actions' Panel.

Types of ERM Sub Forms:

SSA Sub forms *Available under the Project SSA Form (Select* **Site Specific Assessment (SSA) Vic – Western Health***).* *These are submitted directly to the WH Office for Research via ERM*	
SSA Sub Forms	**Description**
Complaint Report VIC	• If a complaint is made about a research project, the site Principal Investigator (PI) must report it to the site Research Governance Officer (RGO). • The site RGO will advise whether the complaint should also be sent to the reviewing Human Research Ethics Committee (HREC).
Site Governance Amendment Request *Click here for Website*	• This Site Governance Amendment Request may be used to notify the site RGO of either: o An amendment that has been approved by the reviewing ethics committee Or o A governance-only amendment that does not require ethical approval This form addresses site governance matters; it is not used to inform the reviewing ethics committee of an amendment. • Amendment that has been approved by the reviewing ethics committee o Submit this Site Governance Amendment Form after the ethics amendment has been approved by the reviewing ethics committee. o You will be required to upload a copy of: ▪ the amendment application that was submitted to the reviewing ethics committee (PDF copy) ▪ the amendment approval letter/email/certificate from the reviewing ethics committee ▪ If applicable, supporting documents approved by the reviewing ethics committee. • Governance-only amendment that does not require ethical approval o Prior to completing this Site Governance Amendment Request form, consult the site RGO to determine whether ethical approval is required o Select this to notify the Office for Research (OfR) any change of personnel. Please note Governance-only amendment that does not require ethical approval cannot be selected for Change of PIs as this will need to be approved by the reviewing HREC
Non-serious Breach/Deviation Report VIC *Click here for Website*	• A deviation is any breach, divergence or departure from the requirements of Good Clinical Practice (GCP) or the protocol that does not have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the research project. If a deviation is considered to be a serious breach it should be reported using the Serious Breach Report (only available under the Human Research Ethics Application (HREA) Form). • To fulfil GCP requirements, any deviation must be reported to the sponsor. Local site policy determines whether a non-serious breach/deviation should be reported to the site RGO. If reporting is required, the sponsor, in collaboration with the site PI, should complete this Non-serious

	Breach/Deviation Report form to inform the site RGO of a non-serious breach/deviation. • Some deviations may require reporting to the reviewing HREC. The RGO will advise whether this is required and, if so, the form should be forwarded to the reviewing HREC. For a multi-site project, the Coordinating Principal Investigator (CPI) should be informed if HREC reporting is required
Site Progress Report *Click here for Website*	This form has to be completed and signed by Principal Investigator along with the WH Self audit Form as part of Annual progress reporting to RGO. Please do not create and complete the Site Audit Report Sub-form.
Site Audit Report	*This form is currently not used by WH OfR – please see the WH Self-Audit Form* here *which should be submitted with your Site Progress Report*
Site Notification Form	*This Site Notification Form can be used for any of the following:* • *Final Report Click here for website* • *Site Closure Report Click here for website* • *Insurance Certificates Click here for website* • *Amendments/Correspondences (Where the Amendment Request Form does not work) Click here for website* • *For any matters which there is no specific post approval form available* *Make sure in the section "For what purpose is this report being submitted?" that you specify the type of submission e.g. "Final Report", "Site Closure Report", "Insurance Certificate" etc.*

HREA Sub forms *Available under the Project HREA Form. These are submitted directly to the Reviewing HREC via ERM*	
HREA Sub Form	**Description**
Ethics Amendment Request	Request ethical approval for a change to the design or conduct of a research project e.g. the protocol, PICF or change to personnel after a research project has been ethically approved. An amendment must not be implemented at a site until the HREC or ethics review body has granted approval of the amendment and (if applicable) the site RGO has granted authorisation of the site governance amendment.
Safety Report *Click here for Website*	Report a safety event to the reviewing ethics committee. The sponsor is responsible for reporting a safety event to the reviewing HREC, in accordance with Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (NHMRC, 2016).
Annual Safety Report	Report to the reviewing ethics committee on the safety profile of an interventional clinical trial only.
Serious Breach Report *Click here for Website*	Report a serious breach to the reviewing ethics committee. This form must be completed by the sponsor. It may be used for reporting a serious breach to the HREC or for providing additional/follow-up information following notification by an individual/institution of a confirmed serious breach.

Suspected Breach Report *Click here for Website*	Report a suspected breach to the reviewing ethics committee. This form must be completed when a third party (e.g. individual or institution) wishes to report a suspected breach of GCP or the protocol. This should be reported directly to the reviewing HREC without reporting through the sponsor.
Project Progress Report	Report to the reviewing ethics committee on the progress of a research project (at least annually, may be more frequent if requested)
Site Closure Report	For a multi-site project, report the closure of one participating site to the reviewing ethics committee. If the research project is completed at all sites approved by the reviewing HREC, use the Project Final Report instead.
Project Final Report	Report to the reviewing ethics committee on the progress of a research project at the time of its completion. This Project Final Report must be used when the research project is completed at all sites approved by the reviewing HREC.
Project Notification Form	Report to the reviewing ethics committee on any matters for which there is not a specific post-approval form available.