Office for Research

GUIDANCE FOR HREA APPLICATIONS – FORMS AND DOCUMENTS

Below is a list of forms/documents required for more than low risk research applications reviewed by PH HREC. This guidance does not apply to multi-site projects approved through SERP or NMA.

New Applications

	Form/Document Name	Mandatory/Project Dependent	Guidance
Ethics Application Form **Ethics Supporting Documents**	Human Research Ethics Application (HREA)	Mandatory for all applications	Complete through ERM. First time users will need to create an account.
	Victorian Specific Module (VSM)	Mandatory for all applications	Addresses Victorian specific legislative requirements not covered in the HREA. The VSM is created as a sub-form of the HREA in ERM. You must upload the VSM within the HREA form in order to submit your application.
	Ethics Payment Form	Mandatory for all applications	Refer to the payment form and complete relevant section.
	Protocol	Mandatory for all applications	Must match the protocol submitted as part of the Low Risk Confirmation. Attach as a supporting document to HREA Application Form.
	Participant Information and Consent Form (PICF)	Project dependent	Templates available from DHHS website. Other PICF formats are not accepted. Templates for Clinical Trials Templates for Health and Medical Research
	Data Collection Tools	Project dependent	This includes questionnaires, surveys, focus group questions/themes, telephone questionnaires. For telephone questionnaires a Telephone Script Template is available.
	Advertising / Recruitment material	Project dependent	This includes letter or email invitations, posters, brochures or leaflets, content for media (including radio, print and digital/social media). See Advertising Guidelines
	Investigator CV for each researcher	Mandatory when a CV has not been submitted in the previous 3 years	Investigator CV Template available Full CV is not required.
	Additional documents for clinical trials	Project dependent	Investigator Brochure / Product Information Instructions for participants Any other documents required under GCP See Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2)
	Projects involving ionising radiation	Project dependent	Contact the Manager Office for Research.
Research Governance Application	Site Specific Assessment (SSA) Form	Mandatory for all applications	Create SSA form as a sub-form of the HREA form using ERM.

Research Governance Supporting Documents	Research Agreement	Project dependent	Refer to Monash Partners Legal Document Repository. Contact the Manager Office for Research if you are unsure if this is required for your project.
	Clinical Trial Notification (CTN)	Project dependent	For projects involving the use of unapproved therapeutic goods. See TGA guidelines. Contact Manager Office for Research.
	Indemnity	Project dependent	Refer to Monash Partners Legal Document Repository. Contact the Manager Office for Research if you are unsure if this is required for your project.
	Certificate of Currency (Insurance)	Project dependent	Must provide sufficient evidence that the commercial sponsor or CRO meets minimum insurance requirements. Contact the Manager Office for Research if you are unsure if this is required for your project.

Post Approval

Below is a list of the post-approval sub-forms which can be created from the **HREA Application** in ERM. Not all available forms are applicable. Please refer to the guidance below:

Form Type	Guidance from form	Use for
Amendment Request	Once a research project has been ethically approved, any change to its design or conduct must be approved by the reviewing HREC or ethics review body. An amendment to a research project may also impact research governance/site specific assessment (SSA). The Research Governance Officer (RGO) at each affected site must be notified of the amendment by the site Principal Investigator (PI), in order to determine if research governance/SSA amendment is required. 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 research governance/SSA amendment.	• Add or amend documents • Change investigator or personnel • Request extension of HREC approval • Reactivate approval • Other (must specify) • Add site *NOTE: Must tick 'Add or amend documents' when adding a new investigator so CV and Change to research personnel form can be uploaded to form. *NOTE: Complete and attach the Ethics Payment Form as part of your submission if the project is commercially sponsored and the amendment relates to a revised protocol or new/amended Investigator's Brochure
Safety Report	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).	
Serious Breach Report	A serious breach is a breach of GCP or the protocol that is likely to affect to a significant degree the safety or rights of a research participant of the reliability and robustness of the data generated in the research project. A serious breach must be notified to the reviewing	• See form guidance

	HREC. The 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. Information on reporting breaches is available in Reporting Serious Breaches of GCP or the Protocol for Trials Involving Therapeutic Goods (NHMRC, 2018).	
Suspected Breach Report	A **suspected breach** is a report that is judged by the reporter as a possible serious breach but has yet to be formally confirmed as a serious breach by the sponsor. This form must be completed when a third party (e.g. individual or institution) wishes to report a suspected breach of Good Clinical Practice (GCP) or the protocol. This should be reported directly to the reviewing HREC without reporting through the sponsor. Information on reporting breaches is available in Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (NHMRC, 2018). A **serious breach** must be notified to the reviewing Human Research Ethics Committee (HREC) using the *Serious Breach Report*.	• See guidance
Project Progress Report	Information on the progress of an approved research project must be provided to the reviewing the Human Research Ethics Committee (HREC) or ethics review body, in accordance with the National Statement on Ethical Conduct in Human Research (NHMRC, 2007).	• See guidance • Submit annually by 1 September • Report should cover the reporting period 1 July – 30 June each year • The Self Audit Tool (SSA sub-form – see below) must be submitted at the same time as the progress report.
Site Closure Report	If an individual site closes from within an ongoing multi-site research project, the reviewing HREC or ethics review body must be notified. This *Site Closure Report* must be used for an **individual site closure in a multi-site research project**. If the research project is completed at all sites approved by the reviewing HREC, use the *Project Final Report* instead.	• See guidance • Not required for single-site projects
Project Final Report	When a research project is completed at all approved sites, the reviewing HREC or ethics review body must be notified. This *Project Final Report* must be used when the research project is completed at **all** sites approved by the reviewing HREC.	• See guidance • For single-site studies that are either abandoned or completed
Project Notification Form	This notification form should be used to inform the reviewing Human Research Ethics Committee (HREC) or ethics review body of pertinent matters for which there is **not** a dedicated reporting form available.	• See guidance • For updated insurance certificates that require submission prior to the progress report submission.

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Below is a list of the post-approval sub-forms which can be created from the **SSA Application** in ERM. Not all available forms are applicable. Please refer to the guidance below:

Form Type	Guidance from form	Use for
Complaint Report	If a complaint is made about a research project, the site Principal Investigator 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).	• See guidance • Applicable for multi-site and single-site projects
Non-Serious Breach/Deviation Report	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*. To fulfil GCP requirements, any deviation must be reported to the **sponsor**. The sponsor, in collaboration with the site Principal Investigator, should complete this *Non-serious Breach/Deviation Report* form to inform the site Research Governance Officer (RGO) of a non-serious breach/deviation. Some deviations may require reporting to the reviewing Human Research Ethics Committee (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 should be informed if HREC reporting is required.	• Site related deviations for multi-site and single-site projects
Site Audit Report	If the site Research Governance Officer (RGO) requests a self-audit report for a research project, the site Principal Investigator should complete this *Site Audit Report*.	• This should be submitted annually at the same time as the annual progress report.
Site Notification Report	This notification form should be used to inform the site Research Governance Officer (RGO) of site matters for which there is **not** a dedicated reporting form available.	• Not required for single-site projects.
Site Progress Report	The site Principal Investigator should report to the site Research Governance Officer (RGO) according to site policy.	• Not required for single-site projects.