|  |  |  |
| --- | --- | --- |
| **ACT Health Directorate HREC Submission Checklist (New submission to full HREC)** | | |
| * Meeting dates and submission deadlines are listed on the Research Ethics and Governance Office [Website](https://health.act.gov.au/research/research-ethics-and-governance/ethics-submission) * Applications must be received by 12 noon on submission day * All applications must be submitted via the REGIS platform * If this study is a clinical trial, registry or bio-bank study, you must have completed the CTMG feasibility assessment process prior to submission * For assistance with REGIS [click here](https://regis.health.nsw.gov.au/how-to/) or call 02 5124 3949 | | |
| **Documents Required** | **Notes and Guidance** | **Submitted** |
| Cover letter signed by the Principal Investigator (not the study coordinator) | * List all sites for which HREC approval is being sought * List all documents submitted, including version control and dates * Only business/institutional emails and mailing addresses should be listed * Indicate if this is a student project * CTN reference where applicable * Clinical Trial Registration Number [ANZCTR](https://www.anzctr.org.au/) or [clinicaltrials.gov](https://clinicaltrials.gov/) | Yes |
| HREA | * HREA completion is managed during the REGIS submission process. For further support please [click here](https://regis.health.nsw.gov.au/media/1423/qrg-resapp-ethics-completing-and-submitting-the-application-v35-final.pdf) * Ensure only business/institutional emails and mailing addresses are listed on the HREA | Yes |
| Study Protocol  [Template available here](https://health.act.gov.au/research/research-ethics-and-governance/site-governance) | * Submission of a study protocol is mandatory * HREA should reference relevant sections of the Protocol | Yes |
| Participant Information Sheet and Consent Form  [Template available here](https://health.act.gov.au/research/research-ethics-and-governance/site-governance) | * For multisite/interstate studies, use the [NHMRC templates](https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources) * For multisite studies, submit a master version and an ACT site specific version * For single-site studies, insert the relevant site logo in the document header. * All study documents must have correct institutional logo [available here](https://www.health.act.gov.au/research/charm-2019/logos) | YesN/A |
| CV’s and GCP Certificates for research team | * Mandatory for all members of the research team interacting with participants * GCP certificates are valid for two years from issue | YesN/A |
| Radiation Safety Report | * Required for any study involving research-specific exposure to radiation that is additional to standard of care * For studies including radiation exposure that is not additional to standard care, please complete the [Ionising Radiation Exposure Statement](file:///Q:\Research\HREG\5.%20Admin\Template%20Forms%20and%20Letters\Radiation%20Safety%20Report\Ionising%20Radiation%20Exposure%20Statement%20-%20Oct%2018_v3.docx) | YesN/A |
| Any other relevant study Documents | * For example: Investigator Brochures, questionnaires, patient cards/diaries, intended advertisement material, Social Media content, letter of invitation, interview questions, telephone scripts * All study documents must include version number/date in footer * All study documents must have correct institutional logo [available here](https://www.health.act.gov.au/research/charm-2019/logos) | YesN/A |
| Therapeutic Goods  Administration Clinical Trial  Notification (CTN) or Clinical Trial Exemption (CTX) form, if applicable | * CTNs must be submitted through the TGA’s online portal. You must not submit a CTN to the TGA until HREC approval is granted. * Include CTN reference in cover letter * For further information [click here](https://www.tga.gov.au/clinical-trials) | YesN/A |
| **Additional Documents for commercially sponsored studies** | | **Submitted** |
| Protocol synopsis | Mandatory for commercially sponsored studies | YesN/A |
| Research Agreement/Contract | Institutional details must be listed as follows:  Name: AUSTRALIAN CAPITAL TERRITORY, the body politic established by section 7 of the Australian Capital territory (Self-Government) Act 1988 represented by Canberra Health Services, Canberra Hospital, Yamba Drive GARRAN ACT 2605 Australia  Address: Yamba Drive, GARRAN ACT 2605, Australia  ABN: 82 049 056 234 | YesN/A |
| Certificate of Insurance | * The insurance certificate must specifically name the Australian Corporate entity acting as commercial sponsor as a named insured under the relevant insurance policy * If the certificate is provided in the name of an overseas parent company, it must name the Australian entity as a subsidiary * The insurance certificate must include a valid coverage period for the policy * The insurer providing the cover must be approved by the Australian Prudential Regulation Authority and must have a minimum financial strength rating of A- or above * The insurance certificate must provide coverage of AUD$20 million for each and every occurrence and AUD$20 million in the annual aggregate against a class of insurance appropriate for the risk associated with the research. | YesN/A |
| Medicines Australia Form of Indemnity  (HREC Review Only) | Only required if study is not being conducted at an ACT site (ie. HREC is providing review only) | YesN/A |
| Financial Summary | * Please contact [Research.Governance@act.gov.au](mailto:Research.Governance@act.gov.au) for referral to finance officer | YesN/A |

Please contact the Research Ethics and Governance Office if you require any assistance with your submission

Email: [ethics@act.gov.au](mailto:ethics@act.gov.au) Phone: 02 5124 3949 or 02 5124 5659