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Research Governance Submission Checklist (Accepting Applications)

This checklist is intended to be used to support research teams in compiling and completing Site Specific Authorisation / Site Authorisation for accepting applications under National Mutual Acceptance (NMA)

It includes required evidence of ethics submission and approval (PART B), Site Specific Authorisation Requirements (PART C)).and additional requirements for Tele-trials (PART D).

This checklist is intended to be used as a guide only. Submissions requirements will vary with each application, it is important to determine the specific requirements for each submission. Submission requirements, including meeting dates and deadlines are outlined in the Alfred Health Ethics and Governance website, if you are unsure of the submission requirements for your application, please contact the ethics and research governance office to access their assistance and support.

Further information about each requirement is hyperlinked within the checklist. Please refer to the following websites for more information.

- ERM website
- Victorian Government Clinical Trials and Research website

Instructions

- This checklist must be completed and emailed with the application to the Ethics & Research Governance Office
- Against each supporting document please indicate the following
    - ☐Yes: Document is required to be submitted and has been included in the application
    - ☐ No: Document is required to be submitted and is still outstanding
    - ☐ NA: Document is not required to be submitted with the application
- The SSA form requires supporting documents to be uploaded in ERM

Part A: Project details and investigator contact details

	Coordinator/Requester	Principal Researcher
Name		
Email		
Department		
Telephone		

	Project Details
HREC Reference Number	
Local Project Number/Protocol Number	
Full Project Title	
Target Clinical Area(s) e.g. ICU	
Campus involved in the project	☐The Alfred ☐Caulfield ☐Melbourne Sexual Health Centre ☐Monash Alfred Psychiatry Research Centre ☐ Sandringham ☐Other (Please specify)

	Local Sponsor Details
Type of Sponsor	☐ Industry ☐ Collaborative Group ☐ Investigator Initiated
Name of Contact	

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Part B: Evidence of Ethics Submission and Approval

The following documents are required to be submitted to demonstrate evidence of ethics submission and approval.

All documents that are submitted should be the latest version

Supporting Documents	Yes	Pending	NA
Ethics Approval and related Correspondence			
• Copy of initial and subsequent Amendment (if any) Ethics Approval Letters/Certificates • Decision-making correspondence between the Reviewing HREC and Co-ordinating Principal Investigator			
Documents approved by the reviewing Ethics Committee			

• The latest version of the core ethics applications documents submitted to the Reviewing HREC including:
• Human Research Ethics Application (HREA)
  ○ Victorian Government Clinical Trials and Research website
• Victorian Specific Module (VSM)
  ○ VSM in ERM guide
  ○ Victorian Government Clinical trials and research website
• Protocol or Project Description			

Consent • Alfred Health Ethics and Research Governance Office • Victorian Government Clinical Trials and Research website			
• Master Participant Information and Consent Form(s): • Master Opt-out information			
• Alfred Health specific Master Information Sheets,			
• Alfred Health specific Master Participant Information and Consent Form(s)			
• Telephone Script (if participants will be contacted by telephone and/or verbal consent sought)			
• e-Consent including screen shot of all information available on electronic devices including PICF			
Research involving participants that are unable to consent • Medical Treatment Decision Maker Checklist • Standard Operating Procedure for participant enrolment or notification • Master Information Sheets			
Drug and/or Device Information • Therapeutic Goods Administration (TGA) • Office of the Gene Technology Regulator (OGTR)			
• Investigator's Brochure or Product Information			
• Consumer Medicine Information			
• Instructions for Use (for devices)			
• TGA ARTG Public Summary (if drug/device is TGA-approved)			
• Office of the Gene Technology Register (OGTR) Licence or Confirmation of Exempt Dealing (if the study involves a Genetically Modified Organism))			
• Information about system (refer to electronic systems section)			
Studies involving Ionising Radiation Procedures: • Alfred Health – Ethics and Research Governance Office • Victorian Department of Health • Victorian Government Clinical Trials and Research website			
• Alfred Health Medical Physicist's Report			
• Alfred Health Victorian Medical Physics Risk Assessment Form – fully signed			

Electronic Systems and Apps • Victorian Government Clinical Trials and Research website (VSM)			
• Screen shot of all information available on electronic devices			
• Product Information for Apps including device system requirements			
• Privacy, Data Security and Terms of Use			
Recruitment and Promotional Material			
• Advertisements			
• Flyers, posters, radio/television scripts, newsletter articles			
• Social media advertisements and platforms to be used			
• Recruitment platform – system details, screenshots, screening questionnaire, consent form (refer to electronic systems section)			
• Letters, emails to potential participants, phone script			
• Webpage materials			
• Referral form			
Other Data Sources/Study Methodology			
• Data Access Policy (for registries/databases/CQRs)			
• Questionnaires, interview guides			
• Recording including methodology/ device used			
• Data dictionary			
• Data collection sheets/Case report forms			
• Data Management Plan			
• Data Custodian approval for projects involving use of established databases			
Retention			
• Participant retention materials			
Participant reimbursement			
• Participant reimbursement materials			
Collection of Biological Samples or Use of Samples from a Biobank • Alfred Health – Ethics and Research Governance Office • NHMRC – National Statement on Ethical Conduct in Human Research			
• Biobank or Samples Access Policy			
• Ethically Defensible Plan (if the research is likely to generate any incidental and/or secondary findings for the participant and/or their genetic relative(s))			
• Approval from custodian of biobank			
Other			
• COVID contingency documents			

PART C: Site Specific Authorisation Requirements

Site Specific Authorisation submission requirements, including meeting dates and deadlines are outlined in the Alfred Health Ethics and Governance website and the Victorian Government Clinical Trials and Research website

The following documents are required to be submitted to obtain Site Specific Authorisation

Supporting Documents	Yes	No	NA
Site Specific Authorisation Submission to Alfred Health:			
• Site Specific Authorisation (SSA) Form			
Legal and regulatory documents • Jurisdictional Legislative Requirements • Quick Reference Table – assists in determining the correct agreement and indemnity to use			
Research Agreements			
• Clinical Trial Preparation Agreement • Medicines Australia Clinical Trial Research Agreement: • Medical Technology Association of Australia (MTAA) Clinical Investigation Research Agreement (Device trials) • Alfred Health Investigator-initiated, company supported • Monash Partners Research Collaboration Agreement • Alfred Health Material Transfer Agreements • Alfred Health Data Transfer Agreement • Clinical Trial Preparation Agreement (“Pre-Nup”) • Student Placement Agreement • Amendments or Addenda to Agreements • Third Party Service Agreements • Alfred Health Research Contract Checklist • Equipment Loan Agreement			
Indemnity Insurance & compensation			

• Insurance Certificate
• Medicines Australia (commercially sponsored and collaborative groups only)
  ○ Medicines Australia Standard Indemnity to Alfred Health for Pharmaceutical Trials Oct 2012
  ○ Medicines Australia HREC review only Indemnity to Reviewing HREC for Pharmaceutical Trials Oct 2012 (copy of the already signed document)
• Medical Technology Association of Australia
  ○ MTAA Standard Indemnity Form for a Clinical Investigation to Alfred Health Apr 2010
• MTAA HREC Review Only Indemnity to Reviewing HREC for a Clinical Investigation HREC Review Only Apr 2010 *(copy of the already signed document)*			

Regulatory documents			
• eCTN Draft or TGA Acknowledgment • TGA ARTG Public Summary			
• Evidence of Alfred Health legal review for non-standard agreements or wording in contracts			
Alfred Health Governance Endorsements			
• Genetically Modified Organisms Advisory Committee /Monash University Institutional Biosafety Committee			
• Data Custodian approval for projects involving use of established databases			
• Clinical Innovations Committee			
• Research Product Introduction			

• Research IT Security Clearance (Digital Health review)			
Use of Alfred Health Resources			
• Use of Alfred Health Resources Form			
• Resource Centre Declarations			
• Baker Heart and Diabetes Institute Imaging			
• Biomedical Engineering			
• Biostatistical Assistance			
• Cardiology Services			
• Clinical Trials Pharmacy			
• Data and Analytical Services			
• General Service Request Form			
Health Information Services • Access to electronic and paper medical records • IT account creation (For CRA & monitor)			
• Intensive Care Services			
• Lung Function Services			
• Nursing Services			
• Pathology & Anatomical Pathology			
• Performance Analysis and Clinical Costing			
• Public Affairs			
• Radiology, Nuclear Medicine and Radiation Oncology			
• Sleep Laboratory			
Head of Supporting Department or Program Approvals			
• Head of Department sign off			
• Emergency Services Research & Education Committee			
• ICU Research Committee			
• Trauma Research Committee			
Qualifications and Training			
• Investigator CV • Evidence of Investigators professional registration • Evidence of Investigators Good Clinical Practice (GCP) Training • Evidence of GMO training			
Fees and charges			
• Ethics & Governance Fee Payment Form			
• Detailed site budget			

PART D: Additional requirements for Tele-trials

Submission requirements for tele-trials are outlined in the Victorian Government Clinical Trials and Research website

Ethics Application Documents			
• Amendment – details of the site PI			
Legal and regulatory documents			
• Standard CTRA tele-trial subcontract (between Primary site and Satellite site) for each Satellite site			
Consent			
• Master Tele-trial Participant Information and Consent Form (based on the primary site PICF) • Satellite site specific Participant Information and Consent Form			
Legal and regulatory documents			
• Standard CTRA tele-trial subcontract (between Primary site and Satellite site) for each Satellite site			
• Agreement between the sponsor and the Primary site – additional wording reflecting use of the Tele-trial model			
Studies involving Ionising Radiation Procedures:			
• Radiation Medical Physicist Risk Assessment			
Qualifications and Training			
• Supervision Plan (between Primary site and Satellite site) for each Satellite site			
• Satellite staff - CV's			
• Satellite staff – Evidence of GCP Training			
• Satellite staff – Evidence of professional registration			
Other			
• Evidence the satellite site Research Governance Office has been notified of the pending submission • Evidence the Principal Investigator has endorsed the conduct of tele-trials at the satellite site			

PART E Additional Documents

As applicable to the research project

Additional Supporting Documents	