Austin Health
Position Description

Position Title: Ethics submission and administrative coordinator

Classification:	HS3
Business Unit/ Department:	The Surgical Anaesthesia and Procedural Medicine Division (SAPM)
Work location:	Austin Health
Agreement:	Victorian Public Health Sector (Health and Allied Services, Managers and Administrative Officers) (Single Interest Employers) Enterprise Agreement 2021 - 2025
Employment Type:	Part-time fixed term (0.4) 16 hours per week
Hours per week:	16 hours per week
Reports to:	Inflammatory Bowel Disease (IBD) Service Lead
Direct Reports:	N/A
Financial management:	N/A
Date:	September 2024

About Austin Health

Austin Health is recognised for high-quality, person-centred care. We're renowned for our specialist work in cancer, transplantation, infectious diseases, obesity, sleep medicine, intensive care medicine, neurology, endocrinology, mental health and rehabilitation.

We're the largest Victorian provider of training for specialist physicians and surgeons, and internationally recognised as a centre of excellence in hospital-based research.

Our services are delivered to patients across four main sites in Melbourne, in locations across our community, in people's homes, and within regional hospitals across Victoria.

We aim to provide an inclusive culture where all staff can contribute to the best of their ability and strive to develop further. We recognise that our people are our greatest strength. We want them to thrive, be their best selves and feel engaged, safe, and empowered. To achieve this, diversity and inclusion is essential to our culture and our values. You can view our current Diversity and Inclusion Plan here.

Commitment to Gender Equality

Austin Health is committed to gender equality in the workplace. In developing our Gender Equality Action Plan we have been guided by the gender equality principles set out in the Gender Equality Act 2020 (Vic). We believe that everyone should live in a safe and equal society, have access to equal power, resources and opportunities and be treated with dignity, respect, and fairness.

About the IBD Service – a sub-specialty of Gastroenterology

The IBD Service has seen significant growth over the past eight years with approximately 1500 patients in its cohort. The service receives new patient referrals across a large regional area, local and interstate referrals of complex patients with IBD and intestinal failure, ulcerative colitis and primary sclerosing cholangitis, as well as paediatric patients transitioning to adult care from the Royal Children's Hospital.

The IBD Service maintains a large research focus that spans basic science, translational medicine and patient management strategies, including clinical trials. We seek to understand the pathophysiology of disease and apply this knowledge to develop enhanced diagnostics and treatments. In addition to this new role, the IBD MDT consists of the Director of IBD, IBD Service Lead, an administration officer, IBD fellow, pharmacist, gastroenterologists, IBD Clinical Nurse Consultants (CNCs), clinical trial coordinators (CTCs), dietitians, colorectal surgeons, pathologists and radiologists who work closely together.

Purpose and Accountabilities

Position Purpose:

To produce quality ethics and governance study applications and ongoing Office for Research (OFR) communications, adhering to the Human Research Ethics Committee (HREC), governance, sponsoring companies, local and international regulatory requirements.

To coordinate administrative activities and operations to support the overall smooth running of clinical research within the IBD Service.

Role Specific:

- Coordinate both sponsored and investigator led IBD clinical trial submissions to facilitate studies through the review to approval process. This may include single site or multi-site submissions, whereby the Austin IBD Service are the lead or a participating site.
- Facilitate obtaining internal and external (if applicable) departmental agreements for new studies.
- Assist the study team with ongoing submissions and communications including though not limited to annual reports, safety reports and protocol amendments to the OFR, sponsors and collaborators as required.
- Working knowledge of, or willingness to learn relevant research guidelines and legislation to ensure correct templates are being used in all submissions.
- Maintain high-quality work and tracking across all levels of the ethics/governance process for the duration of studies from start-up to close-out.
- Communicate and educate sites, sponsors and/or collaborators on relevant processes and timelines relating to ethics and governance submissions.

- For IBD studies whereby Austin is the lead site, assist the primary Clinical Trial Coordinator (CTC) with communicating relevant approvals and study documents in a timely manner to participating sites.
- Assist with the creation of, maintenance of and quality checks for investigator site files (ISFs) in accordance with ICH-GCP, sponsor and regulatory requirements.
- Ensure correct and up to date ethics and governance documentation is filed within departmental SharePoint folders.
- Assist with review and provide feedback on Participant Information and Consent Forms in conjunction with the Principal Investigator, primary CTC, and sponsors/collaborators.
- Assist with progressing trial agreements such as contracts or indemnities as applicable, in liaison with the OFR, legal counsel, sponsors and/or collaborators.
- In conjunction with the IBD Service Lead or primary CTC, assist with facilitating clinical trial budget and agreement processes, including initiating requests to invoice for study payments per contracts.
- In conjunction with the IBD Service Lead or primary CTC, assist with facilitating archiving of studies according to clinical trial, ICH-GCP, departmental and Austin requirements.
- Participate in fortnightly clinical research meetings with the IBD research team.
- Work to tight deadlines and ensure timely follow-up on outstanding matters.
- Assist with Clinical Research Associate (CRA) or auditor set-up and electronic accesses.
- Prepare and submit paperwork for reimbursement of patient expenses.
- Assist with the retrieval of patient's medical information from other health care providers, timely submission of documents to SMR, collation of trial documents or reports.
- Consult with personnel to arrange for servicing and calibration of equipment (ie clinical trials freezer) and maintenance of required logs for study documentation.
- Organize USBs/CDs of patient imaging (for example MRIs or endoscopy videos) for shipping and/or upload to study specific portals as required by trial protocols.
- Depending on the study and training requirements, may assist with basic transcription data entry at the direction of the IBD Service Lead or primary CTC.
- Assist CTCs with set-up and labelling of study sample visit kits if required.
- Assist with any ad-hoc administrative work relating to clinical research at the direction of the IBD Service Lead or Director of IBD.
- Ensure escalations of any urgent study matters to the IBD Service Lead or Director of IBD as appropriate.
- Maintain a flexible approach to managing assigned workload.
- Work to build meaningful and effective relationships with all our internal and external stakeholders.
- Demonstrate a positive attitude to the role and responsibilities of position.

All Employees:

- Comply with Austin Health policies & procedures as amended from time to time.
- Comply with the Code of Conduct and uphold our values, and diversity and inclusion commitments.
- Maintain a safe working environment for yourself, colleagues, and members of the

public by following organizational safety, quality & risk policies and guidelines.
- Escalate concerns regarding safety, quality and risk to the appropriate staff member, if unable to rectify yourself.
- Promote and participate in the evaluation and continuous improvement processes.
- Comply with the principles of person centred care.
- Comply with requirements of National Safety & Quality Health Service Standards and other relevant regulatory requirements.
- Comply with Austin Health mandatory training and continuing professional development requirements.
- Work across multiple sites as per work requirements and/or directed by management.

Selection Criteria

Essential Knowledge and skills:

- Tertiary qualification and/or equivalent experience in an administrative/life science field.
- A commitment to Austin Health values: *Our actions show we care, We bring our best, Together we achieve and We shape the future.*
- Excellent interpersonal and communication skills.
- Excellent organisational skills to prioritize tasks and work well under pressure to meet study deadlines.
- Strong problem-solving ability and demonstrated ability to work independently with limited supervision.
- Enthusiasm, willingness to learn and contribute to the clinical research team.
- Ability to understand technical information and turn it into lay language.
- Proficiency in Microsoft office suite applications especially Word, Excel, Outlook as well as database work and the Internet.

Desirable but not essential:

- Understanding of various research guidelines including the National Mutual Acceptance (NMA) scheme, medical terminology, ICH/GCP and the clinical trials environment; *training can be provided.*
- Experience working in a clinical trial administrative or assistant role.
- A working knowledge of ERM (Ethics Review Manager), the HREA (Human Research Ethics Application) and the SSA (Site Specific Assessment) Form.

General Information

Austin Health is a Child Safe Environment

Austin Health is committed to child safety. We want children to be safe, happy, and empowered. We support and respect all children, as well as our staff and volunteers. Austin

Health has zero tolerance of child abuse, and all allegations and safety concerns will be treated seriously in line with legal obligations and our policies and procedures.

Equal Opportunity Employer

We welcome applications from Aboriginal and Torres Strait Islander people. For any support throughout the recruitment process or further information about working at Austin Health, please follow this link to Aboriginal Employment on our website

Document Review Agreement

Manager Signature	
Employee Signature	
Date	