Cancer Trials Australia
Position Description

Position Details

Position Title:	Ethics Submission Specialist
Manager:	Team Leader – Ethics and Governance
Direct Reports:	Nil
Location:	Victorian Comprehensive Cancer Centre (VCCC) Building, 305 Grattan Street, Parkville and working from home office
Key internal working relationships:	• Operations Manager • Ethics Team • Contracts team • Finance team
Key external working relationships:	• Medical and nursing staff at member site(s), • Site Managers and Study Coordinators, • Supporting departments such as Pathology, Pharmacy • Human Research Ethics Committees(s) and Research Governance Officer(s) and • Pharmaceutical Companies (Sponsor(s))/ Clinical Research Organisations (CROs)

Position Purpose

This role is required to:

- Efficiently prepare and co-ordinate all documentation required to gain Human Research Ethics Committee (HREC) and Research Governance Office (RGO) approval for the clinical trials under the role's administration to a high standard and in accordance with stakeholder and institutional key performance indicators.
- Be the primary point of contact for issues relating to ethics and governance submissions, as well as the status and any feedback related to the clinical trials under the role's administration.
- Accurately and punctually record all ethics submission activities associated with the clinical trials under the role's administration, including associated timelines and trial statuses within relevant databases, and other tracking software/spreadsheets; and
- Provide assistance to, and ad hoc cover for, other team-mates, as and when required, to ensure that agreed service delivery levels are met.

Key Responsibilities

1. Prepare and co-ordinate ethics, governance, and ongoing submissions to the HREC/RGO

- Assist and prepare required Ethics and/or Governance submissions, as per Ethics Committee / Sub-Committee / Directorate requirements (e.g., preparation of the main ethics application form, modification of the Participant Informed Consent Forms, Site Specific Forms, etc.,).
- Notify, and co-ordinate the sign-off of governance submission components by site (e.g., site supporting health service departments such as pharmacy and pathology).
- Coordinate signatures from Site (PIs, Head of Departments).
- Co-ordinate feedback, e.g., in response to queries, to / from HREC / RGO with the Sponsor / PI.
- Co-ordinate document exchange for single and multi-site submissions.
- Identify and proactively address potential delays to clinical trial submissions.

- Submit accurate invoice requests for HREC/RGO fees.
- Update status of clinical trial activity in CTA's Clinical Trial Management System (CTMS) and other relevant tracking spreadsheets/software.

2. Act as a communication link and face of CTA with sites and sponsors / CROs

- Present a professional and positive image at member site and with sponsors / CROs
- Follow up and action sponsor queries in a timely manner.
- Update site and sponsor regarding relevant CTA processes and HREC requirements.
- Advise Team Leader – Ethics and Governance regarding relevant site processes.
- Advise Sponsor regarding study approval processes at site, HREC requirements and related timelines.
- Exchange relevant documentation with sponsor to process submissions.
- Facilitate regular communication between sponsor and HREC / RGO.

3. Administrative Tasks

- Preparation of documents related to each study for the Ethics Team / Site, as delegated.
- Uploading of documents to CTA and / or the member site's shared folder system (E.g., CTA's clinical trial management system)
- Completion of general administrative tasks, as required.

Knowledge, skills, and experience

Qualifications:

The minimum educational, technical, or professional qualifications required to competently perform this role include:

- Tertiary qualification in Health, Life Sciences or other related qualifications, with sound knowledge of medical terminology/ scientific language.

Experience:

- At least 12 months' experience in / exposure to working on ethics / governance processes in a medical administration or clinical research environment.
- Strong organisational and time management skills with the ability to work with a complex set of tasks; to plan and prioritise workload to meet deadlines and work independently, efficiently, and effectively
- Excellent communication and influencing skills with a demonstrated ability to communicate with a wide range of people, including researchers and other external stakeholders.
- Demonstrated experience in the coordination and/or review of Human research ethics applications (preferred)

Skills and Knowledge:

- Ability to develop and maintain professional relationships with team members and external stakeholders.
- Project Coordination in alignment with agreed timelines.
- High level of attention to detail.
- Competent computer literacy skills, including the proficient use of Microsoft Office applications such as Word, Excel, Outlook and Teams.
- Ability to communicate professionally, orally and written.
- High level of organisation skills and time management.

Our Values

All CTA staff are expected to actively support and demonstrate our organisation values in all work activities and interactions.

Shared Purpose

Integrity

Collaboration

Adaptability

Compassion

Acknowledgment

Employee Name: Date:

Employee Signature:

Manager Name: Date:

Manager Signature: