Cancer Trials Australia
Position Description

Position Details

Position Title:	Ethics Submission Specialist
Employment Status:	12-Month Fixed Term, Full Time
Manager:	Clinical Trials Start Up Manager
Direct Reports:	Nil
Location:	Victorian Comprehensive Cancer Centre (VCCC) Building, 305 Grattan Street, Parkville and working from home office
Member Site:	PCCTU
Key internal working relationships:	• Clinical Trails Start Up Manager • Ethics Team and • Contracts 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 • 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

To actively support and demonstrate our organisation values in all work activities and interactions.

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Acknowledgment

Employee Name: Date:

Employee Signature:

Manager Name: Date:

Manager Signature: