Ethics Submission Specialist

POSITION DETAILS

Employment Status:	Fixed Term, Full-time
Location:	CTA office at VCCC / Remote Working
Position initially reports to:	Clinical Trials Start-Up Manager
Effective Date:	March 2022

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.

SCOPE

Financial accountability

(Does this role have accountability for or influence on budget/revenue/assets?)

Direct accountability (detail): Nil

Indirect influence (detail): Nil

Roles reporting to this role

Direct/Indirect: Nil

ORGANISATIONAL CONTEXT

Cancer Trials Australia's vision is to be an international leader in clinical trials, playing a pivotal role in developing new therapies and the advancement of patient care.

Our mission is to be the clinical partner of choice, for its members, industry, research organisations and patients, to provide excellence in clinical trials thereby contributing to Australia's developing knowledge and innovation economy. This will be achieved by**:**

1. Creating a **quality clinical trial framework** that delivers competitive advantage to members and sponsors,
2. Attracting and **advocating for clinical trials to be hosted in Australia**, specifically within member organisations,
3. Ensuring that every trial has the potential to **improve patient care and to build** clinical knowledge,
4. Striving to ensure every clinical trial is conducted to the **highest ethical and clinical standard,** and,
5. Advancing the acquisition and **sharing of knowledge** in clinical trial management, design and implementation across the member network.

SKILLS, KNOWLEDGE & EXPERIENCE

Qualifications:

(The minimum educational, technical or professional qualifications required to competently perform role)

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

Experience:

(What is the minimum level and type of previous work experience required to competently perform role?)

- At least 12 months' experience in / exposure to working on ethics / governance processes in a medical administration or clinical research environment;
- Demonstrated experience in the coordination and/or review of Human research ethics applications (preferred)
- 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

Skills or Knowledge required for the role:

Skill or knowledge area	Level or depth required	Why is it required?
Relationship building / Teamwork	Able to positively influence others to achieve results that are in the best interests of CTA and member sites. Able to work cooperatively and effectively with others to set goals, resolve problem, make decisions, and develop and sustain effective relationships. Obtain and/or provide sound and timely specialist advice and support in areas of the roles' administration and service responsibility.	This role is required to interact daily with a variety of stakeholders, both internally and externally, as a front-line representative of the Company, to contribute to the achievement of CTA objectives.
Computer Literacy	Highly developed computer literacy skills in Microsoft Office applications such as Word and Excel.	This role is required to edit, with confidence and to a high standard, numerous pre-formatted Word documents developed by multiple stakeholders, e.g., participant informed consent forms (PICFs). This role also regularly updates Excel spreadsheets and databases that track the status of clinical trial submissions / amendments.

Skill or knowledge area	Level or depth required	Why is it required?
Project Coordination	Ability to facilitate documents for various stakeholder/s notify and communicate with various stakeholders during the submission and approval phase.	This role is required to coordinate documents required for submission and approval within agreed timelines; this includes an understanding of how these documents, which range from application forms, PICFs, and regulatory forms (e.g., clinical trial notification or CTNs, indemnity and insurance forms), impact on the clinical trial submission / approval process.
Attention to Detail	Ability to accurately review detailed documents containing scientific information and to keep status of multiple submissions/amendments up to date, using various databases / spreadsheets.	Able to read and comprehend clinical trial protocols, and modify PICFs, in order to prepare accurate and timely ethics and governance submissions with a view towards participant involvement in alignment with relevant guidelines and policy, as well as ensuring related databases, and tracking spreadsheets/software are up to date.
Oral & Written communication skills	Ability to communicate effectively within a team, with collaborators and with internal and external stakeholders, both orally and in written form.	This role requires daily communication with internal and external stakeholders. This role requires the incumbent to understand the impact of the amendments received from the sponsor and notify relevant stakeholders.
Time Management / Organisation Skills	Able to meet multiple deadlines successfully.	This role is required to achieve tasks efficiently by effectively managing multiple competing priorities / objectives to meet strict HREC deadlines.

WORKING RELATIONSHIPS:

(Internal positions with which this role is expected to interact on a regular basis)

Key internal working relationships:

Role that the position has regular contact with	Frequency (daily, weekly, etc.)	Purpose/Nature of contact
Clinical Trials Start-Up Manager	**Daily**	To advise on progress of workload, including issues arising from individual trials, member sites or sponsors To escalate issues arising from individual trials, member sites or sponsors as per documented escalation pathway.
Ethics Team	**As required**	Answering queries from, or asking queries of, relevant team members, including acting as a backup resource for colleagues when required
Contracts Team	**As required**	Obtaining contracts and /or querying progress, providing updated departmental quotes

Key external working relationships:

(External positions with which this role is expected to interact on a regular basis)

Role that the position has regular contact with	Frequency (daily, weekly, etc.)	Purpose/Nature of contact
Medical & nursing staff at member site(s) working on a specific clinical trial, e.g., Principal Investigators (PIs), site managers and study coordinators, supporting departments such as pathology, pharmacy etc.	**Daily**	Coordinate trial information, notify and respond to, and follow- up, queries related to progress on trial submissions.
Human Research Ethics Committee(s) and Research Governance Officer(s)	**As required**	Coordinate and submit trial information, respond to, and follow- up, queries related to progress on trial submissions.
Sponsor(s) / Clinical Research Organisations (CROs)	**As required**	Act as a liaison to coordinate submissions, respond to, and follow-up, queries related to progress on trial submissions

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KEY POSITION ACCOUNTABILITIES

(Percentage allocations listed below are indicative only and are subject to fluctuation over any 6 to 12-month period)

1. Prepare and co-ordinate ethics, governance and ongoing submissions to the HREC / RGO - 70% of role

What are the key activities to be carried out?

- 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

What are the expected end-results and how will they be measured?

- To coordinate and submit multiple HREC and Governance submissions to agreed deadlines, including dealing with related queries and gaining approvals, as measured by the:
    - Time taken from submissions to approvals
    - Number of approvals obtained
    - Quality of submissions, and
    - Accuracy and timing of data entered into the CTMS, and tracking spreadsheets/software

2. Act as a communication link and face of CTA with sites and sponsors / CROs - 20% of role

What are the key activities to be carried out?

- 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

What are the expected end-results and how will they be measured?

- Appropriate and timely communication with all stakeholders, as measured by feedback received from site staff and Team Leader – Ethics and Governance (reported either via email, face-to-face meetings and/or other informal interactions), regarding the incumbent's level of productivity and quality of communication.
- Target is: continual positive feedback and engagement from Site / Sponsor

3. Administrative Tasks - 10% of role

What are the key activities to be carried out?

- 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

What are the expected end-results and how will they be measured?

- All relevant documents are placed in required folders in a timely manner
- General administrative tasks are completed within agreed timelines

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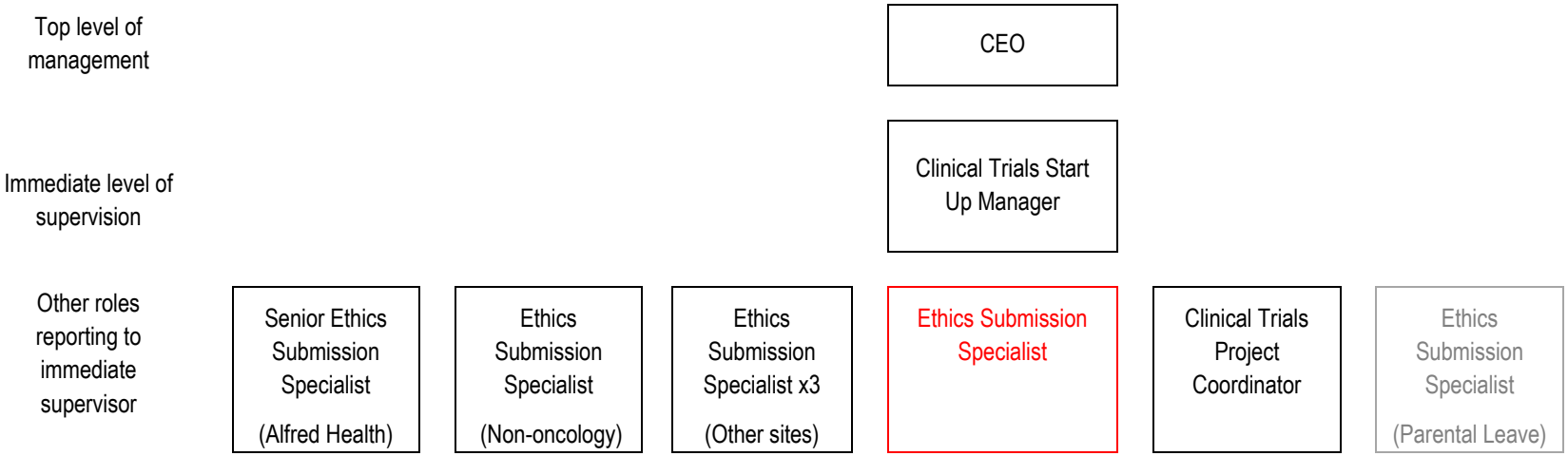
ORGANISATION CHART



Employee Name: _____

Employee Signature: _____ Date: _____

Manager Name: _____

Manager Signature: _____ Date: _____