Position Title:	Clinical Trial Manager
Business Line:	Nursing
Position Reference No.	N0900233
Reporting relationship:	Director of Research, Executive Director

Primary Purpose:

The Clinical Trial Manager (CTM) is accountable for supporting and managing the operations of the clinical trials unit at the Skin and Cancer Foundation Inc. In partnership with the Director of Research, this role requires managing all nursing staff and associated positions, assisting medical, nursing and administrative staff in the provision of clinical trial services and facilitating the coordinator and delivery of patient care in accordance with clinical trial protocols. In association with the Executive Director and Director or Research, the CTM is responsible for assisting in the development of the Clinical Trials annual budget and the ongoing management of the Trials budget. The CTM is also accountable for supporting and maintaining a professional, safe and supportive work environment, and participating in the ongoing development of services.

Principle Responsibilities:

The principle responsibilities of this role are:

- Undertake management of day to day operations of Clinical Trial services
- Management of staff and human resources for trials and ensure appropriate cover/back up
- Management of staff roster and annual leave authorisation
- Resource manage new trials
- Ensure medical/trail supplies are maintained
- Provision of care to clinical trial participants in accordance with ICH/GCP standards and in accordance with Sponsor and HREC approved protocols.
- Participate in the patient recruitment process and identify strategies to achieve patient recruitment targets
- Ensure patients receive appropriate, competent and quality clinical care
- Ensure care is customer/patient focused
- Participate in and facilitate trial monitoring visits and any other visits that may be necessary or relevant to trials
- Facilitate audits by ethics committees, regulatory authorities (including, but not limited to TGA, EMEA and FDA), Sponsor and CRO.
- Participate in feasibility assessments for new trails.

- Assist in the recruitment, training and education of nursing staff
- Train and guide new, or less experienced team members on processes and systems, and provide support as required.
- Undertake staff competency assessments
- Undertake annual staff performance reviews
- Identify and develop ongoing required policies and site written procedures
- Participate in development of annual Clinical Trials budget and its ongoing management
- Management of equipment servicing and maintenance
- Maintain confidentiality of both written and electronic patient/participant information and commitment to ethical standards
- Participate in initiatives and contribute suggestions for improvements and/or efficiencies to enable ongoing quality and continuous improvement
- Assist in identifying opportunities to be cost efficient whilst improving bench marked activities
- Manage and act as a resource for external clinical staff enquiries, complaints and all clinical trial related enquiries
- Work collaboratively with internal and external stakeholders to implement and achieve department goals
- Maintain positive working relationships including a spirit of teamwork with all stakeholders
- Manage Occupational Health and Safety issues that arise
- Manage staff health requirements in association with resident medical officer, as required
- Investigate and manage incidents, ie patient injury, needle stick injury ect.
- Uphold the Skin & Cancer Foundation Inc. values, integrity and good reputation
- Represent Skin & Cancer Foundation Inc. through provision of continuous and consistent excellence in the delivery of customer services
- Understand, apply knowledge and possess an ability to locate all policies and procedures provided by the foundation including compliance with health and safety legislation, workplace initiatives and demonstrate with positive actions in the workplace
- Display commitment and individual responsibility to professional development
- Perform other appropriate duties and responsibilities as assigned

Qualifications:

Bachelor of Nursing

Job Specifications:

Current registration as a Division 1 nurse with the Australian Health Practitioner Regulation Agency (AHPRA)

Knowledge, skills and experience:

The successful applicant is required to:

- Demonstrate proven leadership skills
- Have a minimum of 5 years prior experience in clinical research
- Understanding of the clinical trials industries ethical, legislative and regulatory framework that guides good clinical practice
- Experience in the recruitment, training and education of staff
- Ability to undertake direction from Director of Research and Executive Director
- Possess excellent communication skills, both written and oral, with a highly developed understanding of patient and client needs
- Possess a high level of computer skills
- Be flexible in approach to all undertakings
- Possess a willingness to learn new skills
- Be efficient in time management and organisational skills
- Be honest, trustworthy and possess a high level of integrity
- Be able to work independently whilst having a demonstrated ability to work within a team environment and senior management team
- Interact with patients and members of the public who could display challenging behavior (verbal) and/or a range of emotional expressions

Key Performance Criteria:

The key performance criteria for this role are:

- Ensure clinical trials are run efficiently, effectively and in a professional manner through appropriate staffing and all equipment is maintained to a high standard
- Ability to manage the clinical trials budget and control expenditure
- Manage recruitment, training and education of nursing staff
- Identification and development of policy and procedures to cover all clinical/medical contingencies
- Successful handling of all stakeholder inquiries and complaints
- Ensure medical supplies are maintained at a satisfactory level
- Successful management of workplace incidents
- Develop, maintain and build successful stakeholder relationships
- Ability to manage day-to-day operations of clinical trial services
- Ensure patients/participants receive timely and quality care in accordance with ethically approved protocols.
- Undertake other duties as directed by the Director of Research
- Maintain confidentiality of both written and electronic patient information and commitment to ethical standards of the Foundation

- Maintain a supportive and positive working environment whilst complying with all Foundation policies and procedures and ability to access information as required
- Identify opportunities to be cost efficient whilst improving bench marked activities
- Contribute and participate in staff performance appraisals and undertake annual personal and professional development
- Ensure all activities meet legislative requirements and AHPRA standards and ICH/GCP guidelines
- Ensure health services provided meet statutory requirements and achieve infection control and quality assurance objectives
- Adapts easily to changing business needs, conditions and work responsibilities.
- Adapts approach, goals and methods to achieve successful solutions and results to those of the research department and Foundation objectives
- Is thorough when performing work and conscientious about attention to detail
- Proven record of integrity and commitment to comply with health and safety in the workplace and a commitment to ethical practice including upholding the Skin & Cancer Foundation values and good reputation
- Builds, maintains and provides internal and external customer satisfaction with the services offered by the organisation including providing a high level of customer service
- Earns the trust, respect and confidence of team members and customers through consistent honesty, forthrightness and professionalism in all interactions
- Uses learning techniques to acquire and apply new knowledge and skills appropriate to this position through opportunities for self-learning and development

Security:

In this position there is a requirement to be an Australian citizen or have appropriate visa standard, must be security conscious and have the capacity to work in a secure environment.

Delegation

In the absence of the incumbent, his/her manager shall delegate another staff member of equal authority or higher to undertake the incumbent's responsibilities.

QUALITY, NSQHS & OHS REQUIREMENTS

- As required by legislation, comply with measures in place to ensure the health, safety and welfare of all staff and other stakeholders.
- Lead by example and actively promote a culture of safety in the workplace.
- Ensure the Quality Management Systems & NSQHS standards are implemented to ensure compliance for external certification.
- As required, demonstrate commitment to health and safety through participation in formal and informal discussions, workplace visits and hazard inspections, etc.
- Initiate actions to improve health and safety within area of responsibility.
- Undertake to be proactive in achieving customer satisfaction

Environment:

This position deals with a wide range of tasks. Confidentiality and sensitive handling of information are both strong features of this role as is the ability to be flexible and adaptable.

I ..... (print name) agree that this is a true indication of the duties associated with my role as Clinical Trial Manager. I will abide by the duties listed.

…… (Signature)

…… (Print Name)

…… (Date)