POSITION DESCRIPTION

POSITION TITLE: **Clinical Research Associate**

POSITION LOCATION: **Olivia Newton-John Cancer Research Institute**

EMPLOYMENT TYPE: **Fixed term and part time**

POSITION CONTEXT:

The Olivia Newton-John Cancer Research Institute (ONJCRI) is embedded within the Olivia Newton-John Cancer Wellness & Research Centre. The ONJCRI's mission is to discover and develop breakthrough therapies to help people live better with cancer or defeat it. Our research laboratories sit alongside patient treatment facilities to optimise collaboration between researchers and clinicians. The integration of laboratory and clinic ensures the rapid translation of scientific discoveries into clinical trials for the development of new cancer treatments. The ONJCRI is a global leader in the development of immunotherapies, targeted therapeutics and personalised cancer medicine.

The ONJCRI is the successor to the global Ludwig Cancer Research organisation with a proud track record of a quarter century of collaborative clinical research programs with Austin Health. Much of ONJCRI's strong foundation is built on the Ludwig Cancer Research legacy and through the ONJCRI's exciting partnership with La Trobe University as its School of Cancer Medicine, we play a pivotal role in training Australia's future generations of medical researchers.

The Clinical Research Associate (CRA) will facilitate the implementation, conduct, completion and reporting of clinical studies sponsored by the ONJCRI. This includes trial monitoring, ongoing trial administrative support, and maintaining positive and transparent relationships with key stakeholders including sponsors, contract research organisations, clinicians and government/regulatory bodies.

REPORTING LINES:

This position reports to the Clinical Project Manager. There are no direct reports to this position.

KEY RELATIONSHIPS:

The following key relationships that are an essential component of the position include:

Internal:

Clinical Project Manager
COO
Scientific Director and Medical Director
Program Heads and Program Managers
Clinician Scientists
Scientific Staff
Legal Counsel
Administrative Staff

External:

Austin Health Cancer and Neurosciences CSU Staff
Austin Health Research Office Staff
Pharmaceutical and Biotechnology Companies
Government, including Regulatory Agencies, eg Therapeutic Goods Administration
Academic Institutions, Technology Licensing and Research Offices
Austin Hospital Departments and staff

ACCOUNTABILITIES:

- Ongoing monitoring and support of ONJCRI clinical studies, including:
  - Human research ethics and governance submissions for applicable studies (including laboratory based studies).
  - Drafting and site implementation of Protocols, Informed Consent forms and Investigator Brochures, Case Report Forms.
  - Monitoring of trial-related duties and responsibilities to trial-related staff.
  - Study registration, site initiation, monitoring and management.
  - Establish and maintain Trial Master File and Investigator Site File.
  - Data handling, record keeping, retrieval and clarification, and archiving.
  - Investigator meeting preparation/participation.
  - Safety reporting process for study sites.
  - Study status tracking, study file maintenance and archiving.
- Conduct/attend monitoring visits, including site initiation and close-out visits, as required.
- Contribute to the development of trial specific monitoring procedures and standards and ensure consistent implementation.
- Contribute to the preparation, review, updating and training of Standard Operating Procedures (SOPs).
- Contribute to the preparation and review of all applicable ethics and regulatory documents, and manuals.

AUTHORITY:

Delegated authority is in accordance with ONJCRI policies and procedures.

QUALIFICATIONS:

3+ years experience in clinical research or research administration in the pharmaceutical industry or equivalent. Bachelor Degree, preferably in the Health Science area or RN (or equivalent) is an advantage but equivalent professional experience will be considered.

EXPERIENCE & CAPABILITIES:

- Solid understanding of clinical studies, including protocol development, monitoring, site management and data management
- Experience with Remote Data Capture systems, preferably Medidata RAVE or equivalent.
- Solid knowledge of Good Clinical Practice (GCP) guidelines provided by the International Conference on Harmonsation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and applicable regulatory requirements under the Therapeutic Goods Administration (TGA) and Australian guidelines.
- Ability to perform ICH-GCP and other regulatory compliant monitoring of clinical studies
- Ability to multitask
- Excellent verbal and written communication skills
- Proficient level of computer literacy in MS Office environment