Position description

Position title:	Trial Study Manager
Employer:	Baker Heart and Diabetes Institute
Laboratory:	Diabetes and Vascular Medicine
Supervisor/Manager:	Professor Alicia Jenkins
Date:	8 October 2024

Background

The Baker Heart and Diabetes Institute is an independent, internationally renowned Medical Research Institute focused on cardiovascular disease (including stroke and hypertension), diabetes and their complications, such as kidney disease. We have a long and distinguished history, spanning more than 98 years with our work critical to today's healthcare challenges.

The Baker Institute is well-positioned to address these challenges, with multidisciplinary teams comprising medical specialists, scientists, and public health experts, all focused on translating laboratory findings into new approaches to prevention, treatment and care.

Headquartered in Melbourne, we are a key player in research, translation, education, advocacy and health promotion with a staff of more than 450 (including scientists, clinicians and students). Our senior staff represent us on a broad range of government advisory boards, from health and wellbeing to science and innovation. We also collaborate with leading international research groups as part of our commitment to assisting vulnerable communities around the world.

The Baker Institute is funded through a diverse range of sources including competitive grants, Federal and State Governments, service and clinical income and philanthropic support.

Laboratory

The Diabetes and Vascular Medicine lab has many independent functions and also links with major universities and research institutes in Australia and overseas.

The lab is led by Professor Alicia Jenkins, whose specific research area includes clinical, basic, and translational research in diabetes and vascular medicine, including its prediction and prevention and the use of existent and novel tools for its diagnosis/prevention and treatment.

Nature of environment

Working within a team of study coordinators and study physicians, and collaborating with clinical team for recruitment. The work is deadline and target driven.

Travel requirements

- Travel to meetings related to clinical trials is required. These may be local, elsewhere in Australia, or overseas.

- Travel to Baker Heart and Diabetes Institute clinics for clinical trials may be required. The clinics are located in Melbourne.

Key job requirements, responsibilities and duties

- To conduct clinical trials according to trial protocols:
  - the ICH E6(R2) Note for Guidance on Good Clinical Practice (EMA/CHMP/ICH/135)
  - the conditions of the Human Research Ethics Committee (HREC) approval
  - the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research 2007 (updated May 2015)
  - Baker Institute Human Research Governance team directions
  - terms of the reviewing Human Research Ethics Committee
  - applicable regulatory requirements.
- To collaborate with other centres undertaking the trials.
- To contribute to the research and professional activities of the laboratory.
- To ensure scientific integrity of research work and established data emanating from the research done at or performed at the Baker Institute.
- This role may be directed to perform other duties as directed by the manager/supervisor from time to time and it is a condition of employment that this role complies with any such reasonable requirement.

Specific role and responsibilities

- To organise and co-ordinate the various ongoing clinical studies including completion of case report forms, standard operation procedures, participant care and physician involvement.
- To ensure the studies under supervision are conducted according to good clinical research practice. This includes being audited by external regulatory groups.
- Maintaining confidentiality of participant records.
- To maintain and develop own knowledge and skills in areas of research through appropriate journals and other literature, as well as trial-specific training.

Specific duties

- Co-ordinate designated clinical research studies.
- Identify and recruit potential study participants and screen them for suitability for study trials as per eligibility criteria.
- Carry out all relevant study-related tasks, ensuring adherence to protocol and good clinical practice.
- Perform venepuncture, and deal with handling, processing and storage of blood and urine specimens. This includes maintaining awareness of appropriate blood handling procedures in relation to safety and laboratory techniques.
- Perform study visits on participants as required by the protocol and maintain accurate source documents.

- Manage participant appointments, book clinical research rooms for study visits, book procedures done by collaborating units, as required by the protocol.
- Order consumables for trials and arrange other personnel/resources for trials as required.
- Ensure participant safety during involvement in clinical trials.
- Report Adverse Events/Serious Adverse Events within the timeframes designated for these reports.
- Maintain Drug Accountability records.
- Meet with research investigators and monitors as required for the purpose of assessing the progress of individual studies.
- Enter research data onto designated case report forms and a computerised database.
- Attend specific training days held at various locations (including overseas) designated by study sponsors.
- Perform administrative functions concerned with own area of research and as required by supervisors.
- Participate in Annual Conferences and Seminars involving delegates from all study centres.
- Liaise with drug company research personnel and clinical research associates.
- Involvement in the initiation and preparation of applications for research projects as appropriate, including Human Research Ethics Committee submissions.
- Proactive attendance at team meetings and attendance at all relevant seminars and staff meetings.

Meet statutory requirements of the company

Maintain up to date and accurate knowledge in:

- OHS legislation.
- EEO legislation.
- Privacy legislation.
- Confidential Information Policy.
- Baker Heart and Diabetes Institute Code of Conduct.
- Australian Code for the Responsible Conduct of Research.
- Baker Heart and Diabetes Institute Intellectual Property Agreement.

Requirements of position holder

Education level

- Relevant experience in clinical trials

Experience

Essential

- To be self-motivated.
- Be able to exercise initiative.
- Caring attitude towards study participants.
- Organisational and coordination skills.
- Venepuncture and experience in sample handling and processing.
- ECG measurement experience.
- Intravenous cannulation skills.
- Accuracy of data measurement and recording.
- Attention to detail.
- Experience and ability in previous clinical research studies. Previous experience in this field of diabetes clinical trials will be highly regarded.
- Previous study recruitment experience.

Desirable

- Interest and experience in diabetes and related complications.
- Experience with glucose meters including continuous glucose monitoring.
- Have an understanding of the legal aspects of running a clinical trial.
- Experience in ethics application submission preparation.
- Documented completion of 'Safe Transport of Infectious Substances by Air' Course or other certification meeting the requirements of CASA 92.120 (Infectious Substances, Biological Substances Category B and associated storage and transport media including Dry Ice).

Organisational knowledge

- Perform tasks/assignments which require proficiency in the work area's existing rules, regulations, processes and techniques and understand how they interact with other related functions.
- Able to adapt those procedures and techniques as required to achieve objectives without impacting on other areas.
- Contributes to management and organisational forums.
- Is responsible for service levels to wider organisation from area of expertise.
- Drives development and utilisation of services.

Communication/interpersonal skills

- A high level of interpersonal skills, which enable the appointee to liaise effectively with a wide range of people at a variety of levels internal and external to Baker Heart and Diabetes Institute.
- Excellent oral and written communication skills.

- Demonstrated ability to participate positively in a team.
- Demonstrated ability to maintain confidentiality of participant records.

Knowledge

- Excellent planning and organisational skills, including the ability to manage a range of tasks with conflicting priorities.
- Research experience including awareness of ICH-GCP Guidelines and relevant regulatory / statutory guidelines.

Abilities

- Demonstrated ability to meet deadlines without compromising close attention to detail and accuracy.

Summary of position

This is a position for an experienced Clinical Research Coordinator ideally with experience in the field of diabetes and clinical trials. This is a 4-day (0.8 FTE) appointment.

As the Baker Institute evolves to meet its changing strategic and operational needs and objectives, so will the roles required of its staff members. As such, staff should be aware that this document is not intended to represent the position which the occupant will perform in perpetuity.

This position description is intended to provide an overall view of the incumbent's role as at the date of this statement. In addition to this document, the specifics of the incumbent's role will be described in Key Performance Indicators (KPIs) developed by the incumbent and relevant supervisor as part of the Baker Institute's performance appraisal and development process.

The Baker Institute is an Equal Opportunity Employer and we encourage interest from Aboriginal and Torres Strait Islanders and members of the LGBTIQ+ community for roles within the Institute. We value diversity, inclusivity, gender equity and we promote family-friendly practices. We are a proud recipient of an inaugural Athena SWAN Bronze Award from Science in Australia Gender Equity (SAGE).