POSITION DESCRIPTION

Position Title: Clinical Research Support Officer  
Employer: Baker IDI Heart and Diabetes Institute  
Laboratory/Department: Clinical Research Support Unit  
Domain/Program: Clinical Research Domain  
Supervisor/Manager: Manager, Clinical Research Support Unit  
Date: 9th February 2016

BACKGROUND:

Baker IDI Heart and Diabetes Institute is an independent, internationally renowned medical research facility 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 85 years and our research agenda spans birth to end-of-life health (including maternal health, indigenous and gestational health, subclinical organ damage, heart failure and terminal disease).

Headquartered in Melbourne, with research teams based in Alice Springs and Sydney, we are a key player in research, translation, education, advocacy and health promotion with a staff of more than 650 (including students, honorary staff and visiting academics). Our senior staff represent us on a broad range of government advisory boards, from health and well-being to science and innovation and we collaborate with many leading international research groups as we are committed to a range of international projects that aim to assist vulnerable communities around the world.

Funded through a diverse range of sources including competitive grants, Federal and State Governments, service and clinical income and philanthropic support, we also have commercial subsidiaries that include the early phase trials facility, Nucleus Network.

DEPARTMENT:

The Clinical Research Domain is the ‘human face of Baker IDI’. It provides and supports a range of clinical and research activities that make it a unique facility for human research. A key component of the Clinical Research Domain (the Domain) is its clinical services which encompass consultative, educational, allied health and investigations services across a range of specialities including diabetes, cardiology, respiratory/sleep medicine, ophthalmology and weight management.

In addition the Domain incorporates a number of research support and governance initiatives for the Institute through the Clinical Research Support Unit (CRSU). The Clinical Research Support Unit aims to provide training support, information management, document management, quality management and research governance for all Baker IDI clinical research.

NATURE OF ENVIRONMENT:

A clinical research client oriented environment, encompassing a large and busy clinical research program extending across a range of different specialties and service areas and research support both within the Clinical Research Domain and the Institute more broadly. Staffing includes clinical administrative staff, clinicians, research support staff and researchers. Supporting research projects are permanent, grant specific and casual employees as well as higher degree research students.
SUMMARY OF POSITION:

This is a Clinical Research Support Officer position that requires expertise in clinical research with scope of interest including training support, information management, document management, quality management and research governance.

This position would suit an enthusiastic and experienced clinical researcher, clinical research nurse, or clinical research associate who has excellent communication skills, attention to detail, a strong background in the use of IT systems and who wants to expand their clinical research skills in a more senior role in a dynamic and challenging research environment.

The Clinical Research Support Officer will be responsible for supporting the Manager of the new Clinical Research Support Unit with the day to day management of the function as well as assisting with the ongoing establishment of centralised clinical research services and systems that facilitate the quality and productivity of the growing clinical research program undertaken by the Institute. Core research services and systems supported by this role include training, information management, document management, quality management (including internal audits) and research governance.

SUPERVISORY RESPONSIBILITIES:

- None at this time

KEY CONTACTS:

Internal:
- Manager, Clinical Research Support Unit
- Domain Head, Clinical Research Domain
- Administration and Operational Department Heads
- Researchers

Direct Reports:
- None at this time

External:
- Offsite Baker IDI clinical research staff (e.g. Central Australia)
- AMREP Partners
- Research Institutes
- Victorian Department of Health
- Universities
- Local, state and federal government

TRAVEL REQUIREMENTS:

As required. This is an office based position that may have limited local and occasional interstate travel.

KEY JOB REQUIREMENTS, RESPONSIBILITIES & DUTIES:

- Quality Management - Audits/Monitoring
  - Assist with the establishment of an internal audit program
  - Perform internal audits to confirm compliance with requirements (e.g. Baker IDI Policies & SOPs, Privacy legislation, Good Clinical Practice (GCP), Australian Code for the Responsible Conduct of Research, National Statement on Ethical Conduct in Human Research)
  - Report audit findings and recommendations and ensure corrective and preventative action is taken to facilitate process improvement and development of best practice.
  - As required, carry out other monitoring activities
  - Assist with inspections by external bodies (e.g. regulatory authorities) including pre-inspection and follow-up activities

- Training and Support
o Assist with the development and provision of appropriate training for clinical research staff (e.g. audit findings, GCP, Clinical Research Orientation Training)
o Assist with the maintenance of training information on the learning management system and reporting of training metrics.
o Provision of central GCP and research governance guidance to researchers for study specific issues (e.g. ethics management, protocol deviations, adverse events, complaints) to ensure prompt remedial action and to minimise delays.
o Keep up to date with relevant regulations and guidelines and changes to these. In particular in reference to Privacy legislation, Good Clinical Practice, Australian Code for the Responsible Conduct of Research, National Statement on Ethical Conduct in Human Research

• **Information Management**
o Assist with the establishment and maintenance of up to date information on the CRSU information central repository

• **Document Management**
o Assist with the development and management of a document management system
o Assist with the development of CRSU and Clinical Research Policies, SOPs and templates as required

• **Research Governance**
o Assist with research governance activities as required

• **Administrative**
o Proactive attendance at team meetings and attendance at all relevant seminars and staff meetings
o Liaise with Manager of Clinical Research Support Unit on operational matters as required
o Work co-operatively with relevant researchers and Institute management
o Deal with customer complaints in an efficient, effective and timely manner
o Periodic reporting of research activities where relevant

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.

**MEET STATUTORY REQUIREMENTS OF THE COMPANY:**
Maintain up to date and accurate knowledge in:
• OH&S legislation
• EEO Legislation
• Privacy Legislation
• Confidential Information Policy
• Baker IDI Research Conduct Policies
• Baker IDI Intellectual Property Agreement

**REQUIREMENTS OF POSITION HOLDER**

**EDUCATION LEVEL:**
Perform duties at a skill level which assumes and requires knowledge or training equivalent to:
• A relevant tertiary qualification in biological or health sciences or related discipline

**EXPERIENCE:**
• Graduate with extensive experience in conduct of clinical research, preferably with some experience undertaking clinical research in the commercial sector.
• Considerable experience with Good Clinical Practice, Human Research Ethics Processes, all aspects of the conduct of clinical research.
• Good Clinical Practice current certification or willingness to undertake
• Experience in clinical research audits/monitoring activities, training, information management, document management and research governance would be highly regarded.
• Extensive understanding of relevant research requirements and in particular; Note for Guidance on Good Clinical Practice (CPMP/ICH/135/99), National Statement on Ethical Conduct in Human Research, Australian Code for the Responsible Conduct of Research, Privacy Legislation
• Strong background in the use of computerised systems and proficient in English and MS office applications
• Excellent presentation skills to be able to represent the Institute convincingly at both internal and external meetings.

ORGANISATIONAL KNOWLEDGE:
Detailed knowledge of academic and administrative policies and the interrelationships between a range of policies and activities. Contributes to senior management discussion and decisions.

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 IDI.
• Excellent oral and written communication skills.
• Demonstrated ability to participate positively in a team

KNOWLEDGE:
• Excellent planning and organisational skills, including the ability to manage a range of tasks with conflicting priorities.

ABILITIES:
• Demonstrated ability to meet deadlines without compromising close attention to detail and accuracy.
• Proven ability to work as a member of a team as well as autonomously without close supervision.
• Demonstrated ability and willingness to take initiative and to improve and enhance existing systems and procedures (quality assurance).
• Demonstrated ability to maintain confidentiality and comply with privacy requirements.

As Baker IDI 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 Baker IDI’s performance appraisal and development process.

Last updated 9th February 2016