

Position Description

HR F.1.1.17

Human Research Ethics Committee (HREC) Team Leader

The Bellberry Operations Team delivers high quality, timely, professional HREC services. The Operations Team supports the submission of applications and the delivery of research. The Operations function ensures that Bellberry HRECs can deliver high quality, timely, and consistent research reviews that robustly meet all relevant accreditation requirements.

Role Purpose

The Team Leader will provide efficient and effective scientific and process advice to all users of Bellberry services, conducting preliminary reviews, and developing and implementing new methods and technology within the HREC area to exceed customer requirements and quality standards. Provide effective management, support and direction to a team of HREC Administrators.

Reporting to:

Operations Manager

Objectives

The objectives of this role are to:

- Manage and provide oversight of the operations of a group of Bellberry Human Research Ethics Committees. Proactively manage consistency between Committees within the group, and collaboratively across groups.
- Manage, support and provide direction to a team of HREC Administrators.
- Manage and conduct submission triage and member allocation for HREC meetings in conjunction with other Team Leaders, the Committee Coordinator and Member Manager.
- Ensure drug, device, research, regulatory and policy developments in the research sector are incorporated into Bellberry's policies and reports.
- Maintain a high level of service excellence, and seek opportunities to further improve services in line with our mission of improving the efficiency, effectiveness and quality of research.
- Ensure the integrity of analytical data generated, by adhering to defined protocols for result verification, data entry on eProtocol and registers, and approval of applications.
- Provide effective escalation as agreed with the Operations Manager.
- Ensure the Operations Manager is informed about study issues, and internal and external developments that relate to or may impact on our studies or processes.
- Ensure that work practices are consistent with the requirements of NHMRC National Statement on Ethical Conduct in Human Research 2007.

Key Accountabilities

The key accountabilities of this role to:

Key Accountabilities	Output/Measures
Team Leadership	<ul style="list-style-type: none">• Managing and providing oversight of Bellberry Human Research Ethics Committees.• Leading and managing a team of HREC Administrators.• Providing guidance, advice and support to the HREC Administrators where escalation of scientific, submission and process issues is required.• Delivering site staff and Administrator training and development as required.• Responding to complex and diverse enquiries using expertise and judgement to analyse and solve problems, and provide informed advice and support to the HRECs.• Providing advice and assistance to the Operations Manager, Leadership Team and HREC Administrators.• Working with the Committee Coordinator to ensure that the HRECs are appropriately resourced and supported.• Assisting in the support of new user registrations and invoicing as required.• Ensuring researcher profile documentation is reviewed and that regular searches are conducted to validate researcher profiles, potential conflicts of interest etc.• Escalating issues as required.• Ensuring the Operations Manager (and others as appropriate) are informed of any study issues and internal and external developments that relate to, or impact on, our studies or processes.

Committee Functions	<ul style="list-style-type: none"> • Managing and conducting meeting preparation relating to submission triage, committee member allocation and client submission support. • Reviewing new studies to ensure applications are complete for HREC review. • Working with the Committee member team to identify and allocate appropriate HREC members for meetings, ensuring the relevant expertise for submissions, and where necessary making recommendations for expert review. • Attending HREC meetings to facilitate and guide consistency and identify policy issues. • Monitoring current study timelines and study related issues to maintain quality, consistency and timeliness of reviews. • Attending other relevant meetings as required to support committee processes.
Relationship and scientific support functions	<ul style="list-style-type: none"> • Building relationships with researchers, site staff, and users, or potential users of Bellberry services, in the management and support of submissions, scientific issues, policies and Bellberry processes. • Addressing scientific, policy and process queries for investigators and site staff. • Researching information regarding drugs and devices submitted to determine any restrictions, dangers or other relevant information for the committees or ongoing oversight of studies.
Contribute to continuous improvement by:	<ul style="list-style-type: none"> • Contributing to ensuring appropriate policies and procedures are in place to assist with all office and committee functions. • Supporting the management of change to ensure the ongoing provision of a high-level service. • Contributing to the development and maintenance of appropriate policies and procedures to ensure all governance matters associated with clinical trials are managed appropriately. • Preparing and analysing reports of ethics review processes as required. • Maintaining current knowledge of contemporary trends and developments in research ethics and governance of research, and recommend their application to the Bellberry HREC's where appropriate. • Monitoring relevant regulatory and policy developments to ensure changes are incorporated into HREC policies and procedures.

	<ul style="list-style-type: none"> • Actively participating in, and contributing to, new guides and procedures. • Identifying, assessing and recommending process improvements for administration. • Contributing to having quality system in place and regular audit of internal processes. • Preparing reports as required by the Operations Manager, Chief Executive and Leadership Team.
Ensure a safe working environment by:	<ul style="list-style-type: none"> • Adopting procedures and practices which comply with the Work Health and Safety Act. • Making proper use of all safeguards, safety devices and personal protective equipment (as required in undertaking the duties of the position). • Taking reasonable care to protect the health and safety of self and others. • Ensuring that all accidents and incidents are reported. • Attending training programs to maintain knowledge and awareness of Work Health and Safety practices, as appropriate.
Providing customer service by:	<ul style="list-style-type: none"> • Developing and maintaining sound working relationships with all stakeholders. • Actioning customer requests in a timely and efficient manner. • Ensuring relevant issues are communicated in an effective manner to the team.
Adherence to Bellberry operating procedures and policies, and relevant legislative requirements including:	<ul style="list-style-type: none"> • Ensuring that Bellberry HREC's policies and practices and decisions are consistent with all relevant State and Commonwealth Acts, Regulations, Codes, policies and standards . • NHMRC National Statement on Ethical Conduct in Human Research 2007 and any updates.

Knowledge, Skills & Experience

Foundation knowledge, skills, experience & qualifications	Essential or Desirable
Tertiary Qualifications (Science, Health or Quality Management).	Essential
Demonstrated track record in effectively and efficiently prioritising tasks, and highly effective time management to meet deadlines.	Essential
Excellent oral and written communication skills and ability to effectively transfer technical information to other stakeholders.	Essential
Experience in the use of PCs and software particularly EXCEL and WORD.	Essential
Experience with the administration of, working with or understanding of Human Research Ethics Committees.	Essential
Knowledge and experience of Bellberry processes.	Desirable
Demonstrated experience leading a team.	Desirable
Ability to work as part of a diverse team in a shared working environment	Desirable
Technical understanding and experience of aspects drug development processes.	Desirable
Experience in clinical trial management systems and practices.	Desirable
Knowledge of WHS practices and requirements for a laboratory.	Desirable

Key Stakeholder Relationships

Operations Manager and Bellberry Leadership Team

HREC Administrators

Bellberry Human Research Ethics Committees

External Stakeholders

Support staff across Bellberry

Special Conditions

- Flexible hours and some after hours as required, particularly Wednesday evenings.
- Roster requires on some meeting nights must commence and finish work later e.g. 2pm – 10pm.
- Some intra and interstate travel.
- Leave must be taken to cover a company nominated shutdown period over Christmas/New Year during the closing period over Christmas.