# A more equitable world through better health.





#### POSITION DETAILS

TITLE	Research Ethics and Governance Coordinator
CLASSIFICATION	Professional Level 6.5: \$103,564 + super + salary packaging
TIME FRACTION	Full Time
CONTRACT TYPE	Ongoing
LOCATION	85 Commercial Road, Melbourne 3004, Boonwurrung Land / Work From Home
REPORTS TO	Manager, Research Integrity & Governance
DIRECT REPORTS	Nil
LAST UPDATED	March 25

#### **POSITION SNAPSHOT**

The Research Ethics and Governance Coordinator will work within the Burnet Research Office to assist Burnet researchers in the preparation and submission process of multisite human ethics applications, award and site-specific governance authorisations of approved studies/trials. In addition, this role will coordinate administrative activities and ensure proper governance aspects of the clinical research projects across the Burnet Institute.

Under the general direction of the Manager, Research Integrity and Governance, the position will ensure that Burnet meets its statutory obligations for clinical study/trial governance and compliance with the requirements of the National Statement on Ethical Conduct in Human Research and all applicable regulatory and legal requirements.

#### KEY RESPONSIBILITY AREAS

#### 1. Ethics and Governance

- Efficiently prepare and submit all necessary documentation to gain Human Research Ethics
  Committee and Research Governance Office approval for multisite clinical study/trials on behalf of
  Burnet research team to a high standard, ensuring strict compliance with regulatory requirements.
- Prepare and submit post approval amendments and reports for approved clinical projects.
- Serve as the primary point of contact, co-ordinate queries relating to ethics and governance submissions, as well as the status and any feedback related to the clinical projects with the research
- Assist investigators by providing required Burnet specific documentation for ethics and governance submissions such as Clinical Trials Notification (CTN) submission, Clinical trials Insurance, Data Management Plan, IT risk assessment, health information security, standard operating procedures and other documents as required.
- Assist with progressing trial agreements such as contracts or indemnities as applicable, in liaison with the research team, legal counsel, sponsors and collaborators.
- Identify and proactively address potential delays to clinical trial submissions

#### 2. Administration

- Develop and maintain register of all Human Ethics and governance applications, approvals, changes
  to authorised research personnel, CTNs, agreements, and other required documentation associated
  with the conduct of clinical studies and trials at Burnet.
- Provide administrative advice to researchers submitting ethics application documents by ensuring completeness and appropriate sign-off.
- Provide administrative assistance to submit ethics applications, amendments and reports in a timely manner via the Ethical Review Manager (ERM).
- Provide administrative support to maintain research databases and enter data as required to improve administrative operations within the Research office.
- Develop and maintain a register of personnel and associated good clinical practice certificates, curriculum vitaes, and any other relevant qualifications.

	Develop and maintain a register of progress and final reports.
3. Communication and stakeholder engagement	<ul> <li>Ensure efficient communication between Burnet investigators, research offices, human ethics committees and relevant stakeholders including lived experience consumers and Aboriginal Research Reference Group where required.</li> <li>Manage a high volume of communication to coordinate review of study approval submission and amendments.</li> <li>Excellent organisational skills to prioritize tasks and work well under pressure to meet study deadlines.</li> <li>Ability to develop and maintain professional relationships with team members and external stakeholders.</li> </ul>
4. Compliance & Reporting	<ul> <li>Ensure compliance with relevant Burnet Institute research governance and administrative policies and guidelines.</li> <li>Understanding of various clinical research guidelines including the National Clinical Trials Governance Framework, ICH/GCP, NHMRC National Statement on Ethical Conduct in Human Research and other relevant guidelines and codes and the clinical trials environment.</li> <li>Assist researchers to ensure sponsor and site files are maintained and that teams comply with all relevant standards of the ICH Good Clinical Practice guidelines.</li> <li>Monitor annual report due dates and submissions, assist the clinical team and Sponsor in appraising safety events and serious breaches for their reporting requirements; and carry out administrative functions of the submission.</li> <li>Assist the Research Manager in the investigation of clinical research complaints and breaches in research integrity.</li> <li>Produce standard and ad hoc reports from the research databases to assist in reporting for internal and external compliance and information purposes.</li> </ul>
5. TRAINING	Responsible for completing all required training in line with the position / role.

### **KEY SELECTION CRITERIA**

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1.	Relevant health or science degree	Essential
2.	Sound Knowledge of ICH good clinical practice and NHMRC National Statement on Ethical Conduct in Human Research and relevant regulatory environment applicable to the conduct of clinical research.	Essential
3.	Administrative experience in the preparation and submission of ethics approvals, clinical governance documents and compliance of ethics and governance aspects of clinical trials.	Essential
4.	Ability to maintain excellent stakeholder relationships with a wide range of people, including researchers, Sponsors and collaborators.	Essential
5.	Excellent written and verbal communication skills.	Essential
6.	Strong organisational skills, including the ability manage tasks and meet deadlines.	Essential
7.	Knowledge of medical research translation.	Preferable
8.	Experience using Ethical Review Manager, the HREA (Human Research Ethics Application) and the SSA (Site Specific Assessment) Form, REDCap and office365	Preferable

## **About Burnet Institute**

#### Vision

A more equitable world through better health.

#### Purpose

Create and translate knowledge into better health so no-one is left behind.

#### Values

Respect, Equality, Inclusiveness, Diversity.

#### Who we are

Burnet Institute is an Australian-based medical research and public health institute and international nongovernment organisation that is working towards a more equitable world through better health.

#### What we do

We are committed to creating and translating knowledge into better health so no-one is left behind. We do this through engaging with and understanding the needs of a broad range of communities and stakeholders to develop laboratory-based and social research programs, policies and products that deliver better health outcomes.

#### Where we work



Priority countries:

Australia | Papua New Guinea | Myanmar

We also support and contribute to research and public health programs in other Asian, Pacific and African countries.

#### Australian Institute for Infectious Disease (AIID)

Burnet Institute is a foundation partner of the AIID, a visionary initiative designed to protect Australia and the wider Asia-Pacific region against major global health issues and pandemics. The state-of-the-art facility is expected to be open in 2028 and will be home to Burnet Institute, Doherty Institute and The University of Melbourne, with funding from the Victorian Government. In joining this exciting initiative, Burnet will remain an independent medical research institute.









#### **BURNET 2030 STRATEGY**

The Burnet 2030 Strategy focuses on growing our impact, placing equity at the centre of what we do, and paying close attention to the effects of a rapidly changing climate and environment. Our point of difference is our technical breadth–from laboratory-based discoveries to field research, to commercialisation to development programs; all to progress toward a more equitable world. This is what sets us apart. Our Strategy will also see us invest in our people, building our position as the aspirational workplace within the sector with ethical values and a culture committed to fostering talent for future leadership and rewarding careers.

#### OCCUPATIONAL HEALTH AND SAFETY

The Burnet has a commitment to providing a safe and healthy workplace in accordance with the Occupational Health and Safety Act 2004. All staff are obliged to take all reasonable care to ensure that their actions do not place themselves or others at risk.

#### OTHER REQUIREMENTS

Burnet Institute is a child safe organisation. The incumbent of this position will be required to undergo a Police Check and possibly a Working with Children Check as a condition of employment. The types of contact with children can be viewed <a href="here">here</a>. This position involves the following contact with children (any individual aged under 18 years):

**CONTACT TYPE** 

No Contact With Children

#### **ENQUIRIES**

For enquiries, please contact careers@burnet.edu.au