POSITION DESCRIPTION	
NAME:	**JOB TITLE: Clinical Governance Coordinator**
PRIMARY JOB PURPOSE:	
To assist the COO with the oversight of clinical governance at NeuRA and support researchers conducting clinical trials by (a) putting in place structures and processes to streamline regulatory aspects of trials, (b) monitoring legislative compliance, and (c) assisting researchers conducting clinics and clinical trials at NeuRA to meet their obligations to clinic patients, trial participants, funding sources and regulatory authorities.	
REPORTS TO: (Performance reviewed by):	**JOBS REPORTING TO THIS POSITION:**
COO	Nil

ACCOUNTABILITIES: Key areas of responsibility

The Clinical Governance Coordinator will take responsibility for the following areas within NeuRA:

Clinical Trials

- Establish and maintain relevant Policies and Standard Operating Procedures for clinical trials.
- Advise researchers about, and assist researchers to comply with, regulatory requirements of clinical trials inclusive of but not limited to:
    - ethical approval;
    - CTN notifications;
    - Reporting;
    - Document archiving; and
    - Data archiving.
- Advise researchers about, and assist researchers to implement, ICH-GCP compliant procedures and risk-based monitoring procedures.
- In collaboration with the Administration and Compliance Manager, provide institution-level oversight of clinical trials, monitor and report on clinical trial risks, conduct internal audits, and prepare documentation as required for purposes of risk management, insurance, etc.

Clinics

- Establish and maintain relevant Policies and Standard Operating Procedures for clinics based at the NeuRA site or operated by NeuRA.
- Ensure appropriate mechanisms are in place for clinical services to protect patient privacy, by appropriately administering clinical data management, records management and medical records.
- Establish mechanisms to mitigate and address issues raised in the 2017 clinics review.
- Provide input to the COO and Clinical Governance Committee in relation to the set-up of the Psychosis Tertiary Referral Service Clinic.
- Prepare reports, as directed by the COO, on clinics and clinical trials activities for the Clinical Governance Committee, an Alliance Board sub-committee.
- Liaise with researchers and Finance to ensure set up of appropriate accounts for management of clinic expenditure and income.

Other

- Provide appropriate risk management for risks associated with clinics and clinical trials, maintain a

risk register for them, ensuring mitigation strategies are in place and working and relevant insurance coverage is held.
- Raise areas or issues of concern and provide advice to the COO for clinics and clinical trials for discussion and risk management as required.
- Other duties as required by the COO.

CORE COMPETENCIES/REQUIREMENTS / EXPERIENCE:

- Familiarity with all aspects of clinical trials governance in Australia.
- Experience in providing oversight from a legislative perspective for small low-risk to large higher risk clinical trials including Phase II and Phase III trials.
- Bachelor of Nursing/Science or relevant higher qualification or 3-5 years' experience in clinical research trials and/or clinics.
- A qualification in Health Management or Clinical Research Coordination or equivalent is desirable.
- Prior experience in implementing measures to ensure adherence to clinical trials legislation and appropriate best practice clinical governance.
- Experience in process and systems improvement in a clinical or research environment.
- High degree of proficiency in Microsoft Office.
- High degree of attention to detail.
- Management of clinical risk, professional development and ability to work autonomously within a small operating team.
- Excellent communication and interpersonal skills, with demonstrated ability to communicate effectively and confidently with all levels of staff;
- Highly developed clinical coordination and project management skills;
- Strong clinical judgement, problem solving and decision making skills;
- Demonstrates honesty, integrity and respect;
- Appointment to this position requires proof of qualifications. Certified copies of the required information must be provided prior to the commencement of duties.

KEY RELATIONSHIPS/INTERACTIONS – EXTERNAL AND INTERNAL:

External – Alliance Members (Black Dog Institute, POW Hospital, UNSW), SPHERE clinical trials activity, AAMRI members with clinical trials capabilities.

Internal – Administration & Compliance, WHS, research groups conducting clinical trials and clinics.

WHS RESPONSIBILITIES:

Familiarisation and Compliance with NeuRA general Policies and all NeuRA Work Health and Safety Policies

Responsibilities of all workers:
- Be familiar with and ensure compliance with the WHS Act 2011 and Regulation 2011
- Co-operate with WHS policies and procedures to ensure your own health and safety and that of others within the workplace
- Attend all training sessions as required
- Do not interfere or misuse equipment provided for the health, safety and welfare of persons at work

Additional responsibilities for supervisors: (PCBU)
- Persons Conducting a Business or Undertaking (PCBU) i.e. managers and supervisors, have a duty of care for the health, safety and welfare of all persons in the workplace
- PCBUs must adopt a risk management approach to managing health and safety. This includes undertaking necessary risk assessments
- Attend all required training sessions

NeuRA CODE OF CONDUCT
It is a requirement that all employees within NeuRA are aware of and abide by the Code of Conduct, reflecting the values and standards of the organisation at all times.