

Position Description

Position	Regulatory Advisor
Team / Service	Research Office
Group	Centre of Clinical Excellence
District	Capital, Coast & Hutt Valley
Responsible to	Research Office Manager
Children's Act 2014	This position is not children's worker, requiring a safety check with Ministry of Justice vetting before commencing
Location	This position is expected to work from the Capital, Coast and Hutt Valley District

Te Whatu Ora

The Health System in Aotearoa is entering a period of transformation as we implement the Pae Ora/Healthy Futures vision of a reformed system where people live longer in good health, have improved quality of life, and there is equity between all groups.

We want to build a healthcare system that works collectively and cohesively around a shared set of values and a culture that enables everyone to bring their best to work and feel proud when they go home to their whānau, friends and community. The reforms are expected to achieve five system shifts. These are:

1. The health system will reinforce Te Tiriti principles and obligations
2. All people will be able to access a comprehensive range of support in their local communities to help them stay well
3. Everyone will have equal access to high quality emergency and specialist care when they need it
4. Digital services will provide more people the care they need in their homes and communities
5. Health and care workers will be valued and well-trained for the future health system

Context

Capital, Coast & Hutt Valley district provides hospital and health services in primary, secondary and tertiary healthcare to a total population base of approximately 445,000 citizens.

We are accountable for meeting the needs of and improving health outcomes for all the constituent populations of our district, and the region more broadly. Together we:

[TeWhatuOra.govt.nz](https://www.TeWhatuOra.govt.nz)

Capital, Coast | Private Bag 7902, Newtown, Wellington 6242 | 04 385 5999
Hutt Valley | Private Bag 31907, Lower Hutt 5010 | 04 566 6999

Te Kāwanatanga o Aotearoa
New Zealand Government

- provide secondary and tertiary, medical and surgical hospital services alongside community based health care
- fund local health providers and work collaboratively with the community to create and support multiple health education initiatives and projects within the region
- deliver health services directly as well as contracting external providers
- provide local, sub-regional, regional and national health services as well as community-based health, rehabilitation and support services.

The majority of the district's population live in Wellington and Lower Hutt. The Māori and Pacific populations of Lower Hutt and Wellington are proportionally similar, with the largest Pacific population in the region in Porirua. Kapiti and Upper Hutt have similar numbers of Māori and Pacific people. Most people are enrolled with a GP near their place of residence, so the increasing focus on community-based healthcare is expected to lead to better health outcomes for these population groups. Hutt Hospital provides secondary and some tertiary, medical and surgical hospital services alongside community based health care from its main facility in Lower Hutt City. In addition to funding local health providers and working collaboratively with the community to create and support multiple health education initiatives and projects, Hutt Hospital is the centre for five tertiary regional and sub-regional services - Plastics, Maxillofacial and Burns Services; Rheumatology; Dental Services; Regional Public Health; and Regional (Breast and Cervical) Screening Services.

Wellington Regional Hospital in Newtown is the region's main tertiary hospital with services such as complex specialist and acute procedures, intensive care, cardiac surgery, cancer care, neurosurgery and renal care. The hospital is the key tertiary referral centre for the lower half of the North Island and the upper half of the South Island.

Te Wao Nui, the Child Health Service for the Wellington Region and Central New Zealand based in the new purpose built children's hospital on the Wellington Regional Hospital campus, supports babies to adolescents with medical conditions or who may need paediatric surgery. It provides both hospital and outpatient services.

Women's Health Services provide tertiary level maternity care in Wellington and Hutt Regional Hospitals and a Primary Birthing Unit in Kenepuru. The provision of services from Women's Health encompass community-based primary LMC care and breastfeeding support, and tertiary level obstetrics, gynaecology, and other specialist services.

Kenepuru Community Hospital and Kapiti Health Centre provide secondary and community services based in Porirua and the Kapiti Coast.

MHAIDS is the mental health, addictions and intellectual disability service for the Wairarapa District and Capital, Coast & Hutt Valley District, with multiple specialist facilities. Ratonga Rua-o- Porirua is our forensic, rehabilitation and intellectual disability inpatient unit.

Te Tiriti o Waitangi and Māori Health Outcomes

Māori are the indigenous peoples of Aotearoa. We have particular responsibilities and accountabilities through this founding document of Aotearoa. We value Te Tiriti and have adopted the following four goals, developed by the Ministry of Health, each expressed in terms of mana and the principles of:

- Mana whakahaere** Effective and appropriate stewardship or kaitiakitanga over the health and disability system. This goes beyond the management of assets or resources.
- Mana motuhake** Enabling the right for Māori to be Māori (Māori self-determination); to exercise their authority over their lives, and to live on Māori terms and according to Māori philosophies, values and practices including tikanga Māori.
- Mana tāngata** Achieving equity in health and disability outcomes for Māori across the life course and contributing to Māori wellness.
- Mana Māori** Enabling Ritenga Māori (Māori customary rituals) which are framed by Te Aō Māori (the Māori world), enacted through tikanga Māori (Māori philosophy & customary practices) and encapsulated within mātauranga Māori (Māori knowledge).

We will target, plan and drive our health services to create equity of health care for Māori to attain good health and well-being, while developing partnerships with the wider social sector to support whole of system change.

The Vision, Mission and Values from our District

We bring forward and join our values within our district. These will change as we become a team of teams within Te Whatu Ora.

Hutt Valley

Vision

Whanau Ora ki te Awakairangi: Healthy people, healthy families and healthy communities are so interlinked that it is impossible to identify which one comes first and then leads to another.

Mission

Working together for health and wellbeing.

Ō mātou uara – Values

Mahi Pai 'Can do': Mahi Tahi in Partnership: Mahi Tahi Te Atawhai Tonu Always caring and Mahi Rangatira being our Best

Capital and Coast

Vision

Keeping our community healthy and well

Mission

Together, Improve the Health and Independence of the People of the District

Value

Manaakitanga – Respect, caring, kindness
Kotahitanga – Connection, unity, equity
Rangatiratanga – Autonomy, integrity, excellence

District Responsibility

The district leadership have collective accountability for leading with integrity and transparency a progressive, high performing organisation, aimed at improving the health and independence of the community we serve and achieving equitable outcomes for all. The leadership team are responsible for achieving this aim, aligned with our Region, within the available resources, through a skilled, empowered, motivated and supported workforce in line with government and HNZ policy.

Te Whatu Ora is committed to Te Tiriti o Waitangi principles of partnership, participation, equity and protection by ensuring that guidelines for employment policies and procedures are implemented in a way that recognises Māori cultural practices.

We are committed to supporting the principles of Equal Employment Opportunities (EEO) through the provision and practice of equal access, consideration, and encouragement in the areas of employment, training, career development and promotion for all its employees.

Team/Service Perspective

The Research Office and Clinical Trials Unit (CTU) is located on level 8, Clinical Services Block. The aim of the Research Office is to promote and develop the research culture in the Capital, Coast and Hutt Valley (CCHV) district by supporting researchers and providing robust systems and processes for research projects while also developing close links with external organisations (Medical Research Institute NZ, Universities, etc). CTU is managed by the Research Office and provides office space and clinical trial facilities on a contract basis to Principal Investigators of research projects.

Staff in the unit coordinates pharmaceutical industry and clinical practice group clinical trials. The staff, mainly comprised of registered nurses, also undertake protocol preparation, submissions to regulatory bodies and completion of documentation to ensure compliance with Ministry of Health guidelines and legislations, and appropriate national/international regulations.

Purpose of the role

The Regulatory Advisor role is to provide support for start-up activities such as estimates, feasibilities, ethical and regulatory submissions.

The purpose of the role is to plan, coordinate and administer clinical trials as assigned by the Research Office Manager (ROM). This role is responsible for managing the project life cycle to ensure effective delivery of objectives.

This role ensures that CCHV Policies and Procedures are complied with, and studies are run in accordance with the Protocol, Good Clinical Practice Guidelines (ICH-GCP), Standard Operating Procedures (SOPs) and applicable regulatory requirements.

Key focus of the role are:

- Maintains up to date knowledge, ensures adherence and compliance with local regulatory requirements and associated documentation
- Ensures start up information & requirements are kept up to date in a central repository for project teams.
- Liaise with relevant stakeholders such as sponsors, CROs and internal teams as required.
- Coordinates completion of Confidential Disclosure Agreements (CDAs) and feasibility questionnaire follow up with Departments accordingly to meet deadline.
- Maintains up to date and accurate tracking on the start-up status for each study.
- Provides updates to ROM on a regular basis and communicates any out of scope activities.
- Serves as liaison with ethics coordinator as applicable.
- Coordinates reviews of draft protocols, seeks expert feedback from all Departments.

- Assists with responses to Requests for Proposals (RFP) by developing budget estimates/timelines and feasibility.
- Liaise with stakeholders to provide feasibility assessments as part of RFP.
- Liaise with scheduler to compile timelines as part of RFP.
- Assist with budget Negotiations according to the standardised cost structure/rate sheet.
- Assist with review CTRA document/imbedded finalised budget.
- Assist with review Indemnity document.
- Assist study team in the preparation of study-related documentation.
- Assist with profiles for the Master time table and scheduling studies.
- Manage workflow and workload to meet deadlines.

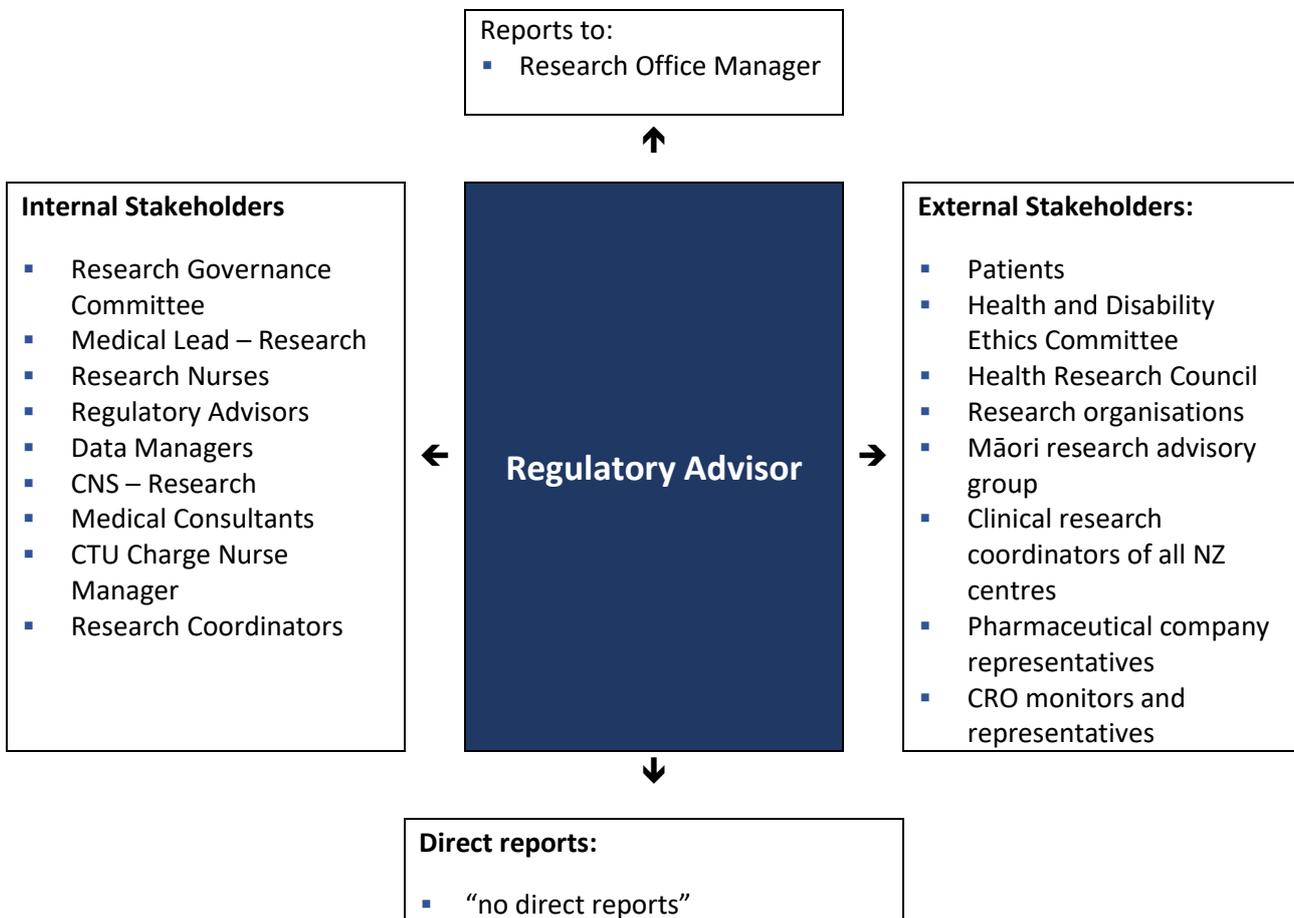
Key Accountabilities

The following role accountabilities may evolve with organisational change and there may be additional duties, relevant to this position that will be required to be performed from time to time.

Key accountabilities	Deliverables / Outcomes
1. Technical outcomes / accountabilities	<ul style="list-style-type: none"> ▪ Relates well to all kinds of people – up, down, and sideways, inside and outside the organisation ▪ Builds appropriate rapport ▪ Builds constructive and effective relationships ▪ Uses diplomacy and tact ▪ Can diffuse even high-tension situations comfortably ▪ Ensures all start up information & requirements are kept up to date in a central repository for project teams
2. Leadership	<ul style="list-style-type: none"> ▪ Can marshal resources (people, funding, material, support) to get things done ▪ Can orchestrate multiple activities at once to accomplish a goal ▪ Uses resources effectively and efficiently ▪ Arranges information and files in a useful manner
3. Stakeholder engagement	<ul style="list-style-type: none"> ▪ Provides education to all groups of health professional staff to raise awareness of ethical and regulatory issues and to enhance their skills for making informed decisions in clinical trial management. ▪ Educates other clinical research staff about regulatory requirements and national and international compliance ▪ Education and management of certain projects or initiatives. ▪ Collaborates with the HDEC and HDEC administrators to ensure the ethical review of the research project is conducted in most efficient manner, public relations activities and to provide training for the research staff to ensure that ethics competencies are maintained and developed. ▪ Maintains a log of education activities and events attended

Key accountabilities	Deliverables / Outcomes
4. Continuous improvement and innovation	<ul style="list-style-type: none"> ▪ Establish a culture of continuous improvement, ensuring linked and cohesive district view of the support services function that identifies opportunities and co-designs innovative solutions to meet the changing needs, from local customers through to district services or whole sector. ▪ Undertakes ongoing education on current regulatory and ethical issues in research ethics and updates the clinical research staff as appropriate. ▪ Tracks metrics and study start-up timelines to identify trends and opportunities for improvement ▪ Maintains up to date knowledge, ensure adherence and compliance with local regulatory requirements and associated documentation
5. Te Tiriti o Waitangi	<ul style="list-style-type: none"> ▪ Work in partnership with stakeholders to achieve our equity goals for Māori and ensure Te Tiriti o Waitangi obligations are adhered to ▪ Equity outcomes are front and centre in goals, performance monitoring and plans for service and team performance ▪ Cultural competence is grown across the team, supporting inclusion and partnership.
6. Health & Safety	<ul style="list-style-type: none"> ▪ Ensure all Health & Safety obligations under the legislation are applied and managed to and that a culture of safe practice is second nature ▪ Actively support and ensure compliance with Health & Safety policy and procedures; ensuring staff also support and comply. ▪ Maintain a proactive culture of Health & Safety supported by systems. ▪ Ensure providers are aware of and have processes to comply with their health and safety responsibilities

Key Relationships & Authorities



Capability Profile

Solid performance in the role requires demonstration of the following competencies. These competencies provide a framework for selection and development.

Competency	Behaviours
Interpersonal Savvy	<ul style="list-style-type: none"> Relates well to all kinds of people – up, down, and sideways, inside and outside the organisation Builds appropriate rapport Builds constructive and effective relationships Uses diplomacy and tact Can diffuse even high-tension situations comfortably

Competency	Behaviours
Organising	<ul style="list-style-type: none"> Can marshal resources (people, funding, material, support) to get things done Can orchestrate multiple activities at once to accomplish a goal Uses resources effectively and efficiently Arranges information and files in a useful manner
Planning	<ul style="list-style-type: none"> Accurately scopes out length and difficulty of tasks and projects Sets objectives and goals Breaks down work into the process steps Develops schedules and task/people assignments Anticipates and adjusts for problems and roadblocks Measures performance against goals Evaluates results
Decision Quality	<ul style="list-style-type: none"> Makes good decisions (without considering how much time it takes) based upon a mixture of analysis, wisdom, experience, and judgement Most of his/her solutions and suggestions turn out to be correct and accurate when judged over time Sought out by others for advice and solutions
Problem Solving	<ul style="list-style-type: none"> Uses rigorous logic and methods to solve difficult problems with effective solutions Probes all fruitful sources for answers Can see hidden problems' Is excellent at honest analysis Looks beyond the obvious and doesn't stop at the first answer
Quality & Innovation	<ul style="list-style-type: none"> Provides quality service to those who rely on one's work. Looks for ways to improve work processes - suggests new ideas and approaches. Explores and trials ideas and suggestions for improvement made by others. Shows commitment to continuous learning and performance development.
Negotiating	<ul style="list-style-type: none"> Can negotiate skilfully in tough situations with both internal and external groups; Can settle differences with minimum noise; Can win concessions without damaging relationships; Can be both direct and forceful as well as diplomatic; Gains trust quickly of other parties to the negotiations; Has a good sense of timing

Experience and Capability

Essential qualifications, skills and experience

A. Knowledge, Skills & Experience:

- 2 years' work experience in the clinical research field and a strong working knowledge of the ICH GCP and FDA guidelines and of the ethical regulations
- Previous healthcare experience is preferred
- Previous experience with investigator start-up documents and investigative sites is preferred
- Experience working with cross functional teams

B. Essential Professional Qualifications / Accreditations / Registrations:

- University degree (Life Science preferred) or certification in a related allied health profession from an appropriate accredited institution (e.g., nursing certification, medical or laboratory technology)
- Prior work experience demonstrating knowledge and understanding of clinical trials, such as that obtained in a clinical trial monitor capacity, and experience managing projects.
- Demonstrated competence in analysis, planning and problem solving.
- Ability to present clear messages from complex information/data to all levels in the organization in both written and spoken English
- Able to make effective decisions, self-motivated, assertive, and displays initiative
- Demonstrated computer literacy, usage of MS Office software, web-based systems and databases

C. Someone well-suited to the role will place a high value on the following:

- Experience in a healthcare setting with patient care, ethics committee operations and guidelines.
- Discovering the truth of things: basing decisions on evidence
- Being a change agent

Ma tini, ma mano, ka rapa te whai
By joining together we will succeed