Job Description

Job Title:	Senior Manager, Research Ethics
Department:	Office of Research
Reports To:	Chief Ethics Officer, Research Ethics
Jobs Reporting:	None
Salary Grade:	USG 12
Effective Date:	June 2017

Primary Purpose

The incumbent has 5 distinct and key responsibilities. In this role, the incumbent is required to:

1. Ensure the ethical acceptability of both minimal and greater than minimal risk human participant research conducted by uWaterloo faculty, staff and students.
2. Ensure the ethical review and acceptability of all uWaterloo research relating to: a) human health oriented research, b) drug/pharmaceutical clinical trial research, c) creation and use of new or novel medical devices, and d) creation and use of new or novel pharmaceutical or natural health products.
3. Assume a leadership role for the Office of Research for all research ethics internal and external communication activities.
4. Develop and manage collaborative institutional review agreements with other institutions provincially and across Canada where applicable (e.g., with WLU and establish processes to streamline the ethics review for researchers).
5. Oversee the delegated and coordinated review processes of minimal risk research conducted at uWaterloo and in collaboration with uWaterloo faculty and staff by developing and establishing processes that are efficient, effective, and address all of the key ethical principles dictated by both federal, provincial, and US regulations, legislation, and guidelines.

Key Accountabilities

On behalf of the two University of Waterloo Research Ethics Committees, the Clinical Research Ethics Committee (CREC) and the Human Research Ethics Committee (HREC), independently conduct delegated ethical reviews and assess research ethics applications for ethical acceptability and compliance with a broad range of international, national, and institutional guidelines:

- Institutional point of contact for the faculties of Applied Health Science, Engineering, Math Science.
- Conduct all delegated ethical reviews for 4 of the 6 uWaterloo faculties, i.e., Applied Health Science, Engineering, Math, and Science, to ensure ethical acceptability of this research and continued ethical acceptability via approval of modifications and annual renewals.
- Identify opportunities to clarify international, national, and institutional requirements via the development of new guidelines or standard operating procedures, particularly in areas involving biomedical research.
- Ensure compliance with a broad range of US FDA, US NIH, US OHRP, ICH-GCP, Tri-agency and Health Canada requirements for health related research, clinical trials, medical devices, and drug/pharmaceutical and natural health product trials, which affect uWaterloo funding, liability and reputation.

Independently manage the administrative process and operations of the Clinical Research Ethics Committee (CREC):

- Ensure operational processes are in place to enhance and support uWaterloo's ability to conduct health research, clinical trials (Phases 1 – 4) and other health related research such as the creation and use of new or novel medical devices, drugs/pharmaceuticals and natural health products.
- Apply subjective judgment and nuanced risk assessment techniques to assess applications to decide on appropriate review route (i.e. decide if committee or delegated review).
- Serve as secretariat for CREC to ensure conformity with federal (e.g. TCPS), US (e.g., FDA) and institutional (e.g. Terms of Reference) requirements for the administration and operation of CREC.

- Ensure agendas, minutes, and feedback to researchers are accurate, complete and produced in a timely manner.
- Research complex technical research processes and issues associated with conducting clinical trials and health research in order to provide advice to CREC and uWaterloo researchers as required. Many processes involve vulnerable populations, new technologies and emerging methods not yet regulated by appropriate agencies (e.g. researcher developed medical device equipment, use of nano-materials such as quantum dots, bio-banks and genetic repositories) and sensitive issues regarding privacy and confidentiality of health and other information.
- Anticipate issues and ensure appropriate background information is available to facilitate CREC decision making.
- Foster effective working relationships with Chair and CREC members.
- Ensure effective and efficient CREC operations; anticipate emerging issues.
- Identify opportunities for ongoing professional development for CREC members.
- Conduct all committee member orientations and monitor quality of CREC reviews to ensure required technical competencies.
- Identify areas which may create extraordinary risk or institutional liability and problem solve and develop possible solutions with the CREC Chair and Director, ORE.
- Screen protocols for non-compliance with institutional or other provincial, federal, international, or US compliance obligations and provide guidance to researchers and CREC.
- Produce annual activity reports on CREC activities for Chief Ethics Officer and inclusion into ORE annual report.

Assume leadership role for the development of new and revised ORE operational guidelines and SOPs related to delegated and coordinated review to ensure conformity with international, national and institutional requirements:

- Conduct complex analysis in areas where conflicting requirements exist or where compliance requirements are unclear (e.g. ICH – Good clinical practice, US FDA, US NIH, Health Canada, TCPS, provincial Controlled Acts legislation) and recommend solutions.
- Invent new processes in areas where no standard approaches exist or where compliance obligations are unclear or ambiguous (e.g. controlled acts, what requires ethics review, data collection exempt from ethics review, and course based research). This may involve negotiation and clarification of discrepancies among existing departmental processes e.g. IAP, development, research.
- Independently develop standard operating procedures which may involve coordinating processes between multiple institutions to avoid incurring new institutional liability while still meeting compliance obligations (e.g., WLU and uWaterloo; Tri-hospital Research Ethics Board and uWaterloo).
- Negotiate and resolve institutional conflicts and sensitivities with faculties where new or revised guidelines will create new accountabilities or processes (e.g. controlled acts; sex-based differences in research).
- Ensure ORE operational guidelines reflect best practices for ethical review from national and international perspectives (e.g., Good Clinical Practice, ICH).
- Secure internal ORE, uWaterloo (e.g., Secretariat, researcher, Chairs/Deans, Institutional Analysis and Planning (IAP), Survey Advisory Board, and Centre for Teaching Excellence (CTE) and both Research Ethics Committees (REC) (i.e., HREC and CREC) approval for recommended changes to guidelines and SOPs, as appropriate. This position is the Office of Research Ethics point of contact with IAP (and the survey advisory board) and CTE.
- Update all internal ORE SOPs related to CREC (500 series) and delegated review (200 series) to ensure accurate and efficient process and appropriate compliance and quality control.
- Initiate new series of ORE SOPs and develop all SOPs required for coordinated review (600 series) with other institutions.
- Initiate and manage the uWaterloo Research Ethics and Integrity Advisory Committee

Directly supervises the Research Ethics Coordinator including contract/casual staff, and co-op students:

- Ensures job description is accurate and current and conduct annual performance evaluation.
- Make decisions regarding hiring, firing, promotion and discipline as required (including orientation, training, and ongoing development).

- Develop annual objectives that are measurable and reasonable to support ORE objectives and supervise daily performance.
- Ensure appropriate levels of job enrichment and enlargement.
- Recommend changes to job responsibilities and job description as appropriate.

Fulfill a public relations and outreach role with both internal (e.g., faculties, departments, Schools, and affiliated Colleges) and external (e.g., CAREB Ontario) audiences:

- Represent uWaterloo professionally at regional and provincial conferences and informal networking events.
- Initiate and manage regional networking events involving other regional universities e.g. Macmaster, WLU, Western.
- Initiate activities to enhance the profile of uWaterloo's ORE within region and province by participating on other REBs and committees e.g. Waterloo Region Public Health REB.
- Provide seminars, speaking engagements to both internal and external audiences.
- Develop effective working relationships with relevant bodies and associations both within and outside of the organization (e.g. Health Canada, CAREB, local universities, uWaterloo Secretariat, faculties, departments, schools, affiliated Colleges, and uWaterloo Institutional Analysis and Planning).
- Develop and manage the annual communications plan for the ORE including the assessment of gaps and the identification of key initiatives and timelines.
- Design the ORE website and ensure the content is up to date and meets institutional accessibility requirements by delegating required updates to other ORE personnel as appropriate (e.g. Manager ORE, REO, casual help).
- Prepare ORE newsletter at least once a year for broader uWaterloo community.
- Develop standard ORE communications initiatives utilizing technology as appropriate (e.g. webinars, Learn).
- Organize, administer and participate in ad hoc committees as needed for research activities
- Prepare non-routine reports as requested by supervisor, uWaterloo leadership team or other committees, Research Ethics Committees, etc.
- Attend meetings on and off the University campus with other research ethics managers/administrators, researchers, government officials, and prepare written and make oral presentations as required.
- Undertake special projects as requested by supervisor, Research Ethics Committees, Institutional Analysis and Planning, or other departments or committees as needed (e.g., Brand Management with VP of Marketing and Recruitment).

Provide leadership and conduct process analysis for all forms of delegated and coordinated (e.g. WLU, THREB) reviews and to identify tactical opportunities to further delegate undergraduate and course-based research reviews while maintaining the quality of ethical reviews at uWaterloo:

- Initiate discussions and launch new committees and processes for delegated or coordinated reviews (e.g. departmental review committees after approval by Director and appropriate REC).
- Ensure appropriate delegations or coordination being done where and how most efficient.
- Monitor operations of delegated and coordinated review to ensure efficiency and effectiveness of delegated review processes.
- Develop standardization of processes including standard operating procedures to maintain full compliance with TCSP obligations.
- Ensure quality assurance checks are sufficient and appropriate to maintain consistency of reviews.

Provide support, assistance, and backup for the Chief Ethics Officer when appropriate.

Required Qualifications

Education

- Completion of a Master's degree in a discipline related to clinical and health oriented research; professional designation related to clinical research or ethics review an asset e.g. Certified Clinical Research Associate from McMaster.

Experience

- 10 or more years of clinical and/or humanities research experience
- Well versed in research ethics, the TCPS2, and the conduct of research studies in varied settings

- Progressive project management and/or other business experience with a proven track-record including simultaneous management of multiple projects and direct supervision of personnel.
- Independent, proactive administrator with exceptional communication (oral and written), organizational and presentation skills, ensuring effective interaction broadly within the University and with external agencies.
- Must have initiative, the ability to be flexible, and strong problem-solving skills.
- Strong analytical skills, be able to interpret accurately, and apply agency and institutional regulations, policies and guidelines.
- The ability to work with confidential information, to work independently and as part of a team, and the capacity to work effectively and efficiently in a complex, fast-paced and changing environment with numerous deadlines and priorities is essential.

Knowledge/Skills/Abilities

- Research and project management experience overseeing multiple projects at any given time
- Research ethics administrative experience
- Direct supervisory experience managing a team
- Competencies will include strategic thinking, people management, conflict resolutions, persuasion, interpersonal, organizational and communication skills.
- Excellent working knowledge of the TCPS2, ICH: Good Clinical Practice, PHIPA, Health Canada Division 5

Nature and Scope

- **Contacts:** Internally, communicates with all employees in all groups and departments and at all levels to deal with, influence and motivate others, and to promote, justify and settle highly sensitive matters. Externally, this position will have significant senior contacts with other universities and regulatory bodies and will be involved in settling highly sensitive, confidential matters that are critical to the organization.
- **Level of Responsibility:** The position is responsible and accountable for ensuring uWaterloo Research Ethics Committee (i.e., CREC) operations are effective and compliant. Initiate self-development activities to ensure knowledge is current and complete.
- **Decision-Making Authority:** Responsible and accountable for establishing the priorities for the department and addressing the changes to departmental plans by consulting directly with the Director and REC Chairs as appropriate.
- **Physical and Sensory Demands**: Minimal demands typical of a management position operating within an office environment.
- **Working Environment:** Minimal exposure to disagreeable conditions typical of a managerial position exposed to stress and pressure; may frequently attend networking and other meetings in external locations; required to attend off site meetings and evening meetings.