

Job Description

Job Title:	Research Ethics Advisor
Department:	Office of Research
Reports To:	Senior Manager, Research Ethics
Jobs Reporting:	Co-op Student(s)
Salary Grade:	USG 9
Effective Date:	October 2019

Primary Purpose

The Research Ethics Advisor (REA) serves as the primary liaison between the Office of Research Ethics (ORE) and the researcher and his/her research team. The REA is responsible for facilitating the research ethics submission and review process and overseeing the effectiveness and efficiency of the online ethics review system. The REA ensures that the daily operations comply with internal and external requirements. The REA roles support the four research ethics review committees and two advisory committees along with internal and external stakeholders (e.g., researchers, government agencies, accreditation committees/auditors, faculty/department and other administrative staff) regarding the requirements for and outcomes of the ethics review of proposed research. The REA is responsible for developing reports and tracking required information to establish performance metrics for the ORE.

Key Accountabilities

Facilitate and conduct ethical analysis of research

- Point person for all inquiries and questions regarding research compliance obligations including the requirements and processes involved with obtaining and maintaining ethics clearance.
- Provides consultation to faculty, student and staff researchers regarding the ethics review process and the required ethical obligations according to institutional, national and provincial requirements and guidelines
- Conducts delegated review of specified minimal risk ethics applications
- Reviews revisions of designated research ethics applications to ensure the reviewers' comments have been addressed, meet the required ethical requirements and guidelines, and recommend approval for the research to proceed
- Reviews amendments/modifications of protocols/ethics applications to assess risk level and recommend approval for the change to be made to the research
- Promptly and effectively respond to all telephone, mail, and email/web inquiries and questions from faculty, staff, students from any of the six faculties, affiliated Colleges or research institutes, including non-Waterloo researchers or partners regarding research compliance including the ethics review process and administrative requirements
- Provides advice and assistance about Waterloo's research ethics process, guidelines, policies and other information as needed by relaying it clearly and accurately
- Interprets international, federal, provincial, and institutional policies and procedures as it related to Waterloo's ethics review process and communicate these policies and procedures to researchers, staff, and students
- Maintains professionalism at all times in conflict situations; use interpersonal skills to handle sensitive and delicate situations and cases (e.g., where research grant support is conditional upon ethics clearance or when an application is time-sensitive or in need of review by multiple offices/levels (e.g., Safety Office)

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- Develops and maintains positive working relationships directly with researchers and ethics committee and advisory committee members to build credibility and encourage proactive discussions and anticipatory analysis of ethical issues in the application undergoing review
- Makes recommendations to supervisor on ways to clarify ethical research compliance requirements then draft new guidelines or standard operating procedures that interpret these compliance requirements for Waterloo researchers for review by managers
- Unique to the REA for human research:
 - Establishes, recruits, trains, and monitors the quality, and day to day operations and ethical reviews of the course-based research Delegated Ethics Review Committee according to the terms of reference
- Unique to the REA for animal research:
 - Oversees the coordination of the post-approval monitoring program in collaboration with the Senior Animal Health Technician – PAM
 - Coordinates Animal Care Committee (ACC) tours and inspections by Consulting Veterinarian, Ontario Ministry of Agriculture and Rural Affairs (OMAFRA) and Canadian Council on Animal Care (CCAC) including the maintenance of records, distribution of reports associated with tours and inspection, and monitors responses and follows through on any required actions
- Applies procedures for effective monitoring of animal purchases with UWaterloo Purchasing office

Utilize Business Tools, Resources and Processes

- Independently applies standard operating procedures and guidelines to decide on the ethics review route (i.e., either single person delegated, committee delegated or full committee as appropriate) based on several factors and criteria and triages all incoming events (e.g., new applications, annual continuing review, adverse events/incidents, modification, post approval monitoring, protocol deviations, incidental findings)
- Develops standard operating procedures for back office operations including the Central Animal Facility and other satellite facilities
- Reviews applications for completeness and compliance with submission requirements
- Coordinates the timely review of all research ethics applications through all stages of the ethics clearance process.
- Verifies that the required ethics training has been completed by Waterloo researchers named on applications and communicate to researchers if this training has not been completed
- Maintains the integrity of all electronic and paper files and documents including the input of information into ethics system, auditing of records and files, following up with researchers for outstanding or missing information/documents, unapproved submission, and annual progress reports or suspended/lapsed approvals
- Coordinates the ordering and renewal of key journal subscriptions accreditation/memberships for ORE staff, and maintenance of a library
- Produces a pre-determined list of ongoing descriptive statistical reports concerning key operational benchmarks

Provide Stakeholder Support and Influence

- Provides day-to-day operational and secretariat support to the research ethics and advisory committees by preparing the agenda and minutes, ordering meals, taking care of room bookings and equipment or IT requests
- Maintains up to date committee files such as membership lists, reports, terms of reference, minutes, and orientation materials
- Coordinates and prepares ethics staff and committee members for site visits from external provincial or federal audit/compliance teams. This includes the advance preparation of audit reports and other

supporting documentation, anticipating questions/issues, explaining specific ethics processes, forms, and templates, and following-up with requests from auditors for additional information or reports

- Communicates and troubleshoots with researchers regarding non-compliant or incomplete paperwork
- Synthesizes required external reports involving external agencies' operational audits
- Manages internal and external inspections and national or provincial audit or site-visits
- Clearly communicates and explains compliance requirements for common international, federal, and provincial regulations and relevant University of Waterloo policies and procedures arising from stakeholders
- Participates in developing content for ongoing communication initiatives

Demonstrate business knowledge

- Identified sources from which to obtain required information concerning grants, financial obligations, institutional policies
- Manages special events such as annual meetings

Support Ethics Administration System

- Oversees the maintenance and monitors the functioning of the ethics review system and be the point person with the Office of Research Information Systems Specialist and Computer Systems Specialist by advising
- Ensures system workflow reflects Standard Operating Procedures (SOPs) for back office and Committee operations and required use of system/database for users and administrators; notify Senior Manager if gaps identified
- Establishes, monitors, and updates the system site for all Committees
- Trains Committee members to use the system site, troubleshoot problems, and prepare instructional materials as needed
- Maintains a current and complete list of relevant SOPs, policies, and professional development materials are available and accessible for Committee members
- Monitors and maintains the internal drive for file sharing (R drive) to ensure the structure is efficient and appropriate to meet the needs of the ethics office staff
- Liaises with Office of Research Operations and Communications staff to identify changes which need to be made on the human and animal websites with respect to development, maintenance, and upgrades
- Decides on record retention and destruction according to uWaterloo and ORE guidelines
- Unique to the REA for animal research:
 - Ensures animal purchases do not exceed approved limits

Deliver Training and Development

- Conducts orientation for new committee members
- Develops materials for workshops or training sessions
 - Leads ethics and integrity compliance training sessions for small to medium sized audiences
 - Assists in the design and development of training content where relevant (e.g., completing an application)
 - Identifies areas where training is needed and proposes ideas to ORE team concerning new training initiatives or needs
 - Assists in analyzing feedback received from training sessions for the purposes of improving future training sessions
- Unique to the REA for animal research:
 - Develops schedules for training sessions ensuring trainers have been secured for each session in a timely fashion

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- Manages the Desire2Learn (D2L) and Workday registrations and course content for all animal training.

**All employees of the University are expected to follow University and departmental health and safety policy, procedures and work practices at all times. Employees are also responsible for the completion of all health and safety training, as assigned. Employees with staff supervision and/or management responsibilities will ensure that assigned staff abide by the above, and actively identify, assess and correct health and safety hazards, as required.*

Required Qualifications

<p>Education</p> <ul style="list-style-type: none"> • A university degree in a research related field (health sciences or social sciences is preferred) or advanced diploma which involved a research course or project involving human participants or animals OR Equivalent extensive ethics administration or research administration and experience at the coordinator level, (5-7 years) OR Completion of relevant professional designation in ethics or research administration plus 3-5 years' experience in ethics administration.
<p>Experience</p> <ul style="list-style-type: none"> • 3 to 7 years' experience in ethics administration or research administration.
<p>Knowledge/Skills/Abilities</p> <ul style="list-style-type: none"> • Human Research: TCPS2 CORE tutorial CITI Canada – Good Clinical Practice CITI Canada – Social Sciences and Humanities Module Animal Research: AR0001 – Basic Animal Research Theory AR0004, AR0010 CAF Orientation Theory and Tour AR0014 – Advanced Animal Research – Theory; uWaterloo Mandatory Courses: SO1001 – Safety Office Orientation SO1081 – Safety Office Workplace Violence Integrity matters (OHD 120) • Basic skills in Microsoft Office suite • Sharepoint at basic level (SEW 090) • Prior use of an online, web based system • Experience in a customer service role (e.g., OHD Inclusivity Certificate)

Nature and Scope

- **Contacts:** . Communicates internally with faculty, staff, and student researchers. Will respond to questions, inquiries, and provide information regarding ethical concerns. External contacts may include Ethics Committees/Boards.
- **Level of Responsibility:** Demonstrated ability to plan and carry out the implementation of large projects. Independently, establish multiple priorities and meet established deadlines with little direction.
- **Decision-Making Authority:** Demonstrate refined and capable professional judgment based on relevant facts and guidelines; independently make decisions during the ethical compliance review of protocols about non-compliance issues and recommend solutions. Assist less experienced researchers and team members with problem solving and developing effective solutions to ethical dilemmas. Demonstrate refined and capable professional judgment based on relevant facts and eligibility guidelines.
- **Physical and Sensory Demands:** This job requires a keen attention to detail. The incumbent must have an ability to handle numerous disruptions and occasional situations involving conflict or individuals who may be rude, unreasonable or upset. Intermittent to prolonged periods of keyboarding to word process documents or enter data.
- **Working Environment:** Experience working in an academic environment In-depth knowledge of the key research ethics and integrity business processes. Broad knowledge of the functional areas and processes within the Office of Research Ethics. Basic knowledge of the working of the broader uWaterloo departments. Detailed knowledge of relevant uWaterloo and Office of Research Ethics

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policies and procedures on either the human or the animal side. Understanding of the distinction between sponsor guidelines, externally mandated compliance obligations, and uWaterloo policies. General familiarity with research integrity process.