



Ethics Clearance for Research with Human Participants and Responsible Conduct of Research at the University of Waterloo

Computer Science 697 Graduate Students

Monday November 7, 2016

Sacha Geer, PhD Manager, Office of Research Ethics (ORE)



**UNIVERSITY OF
WATERLOO**

Learning objectives

1. Recognize when ethics clearance is required for research with human participants
2. Distinguish between research integrity and academic integrity processes and obligations
3. Recognize behaviours which may be considered a breach to the RCR framework and discuss how Canada's RCR system is unique globally
4. Identify when and how to report a breach to the RCR framework
5. Recommend strategies to students and colleague to avoid allegations of breaches to RCR framework

- Computer Scientists are increasingly collaborating across disciplinary boundaries, or creating projects which need to be tested with human participants.
 - It's important to know what sorts of activities may require ethics clearance.

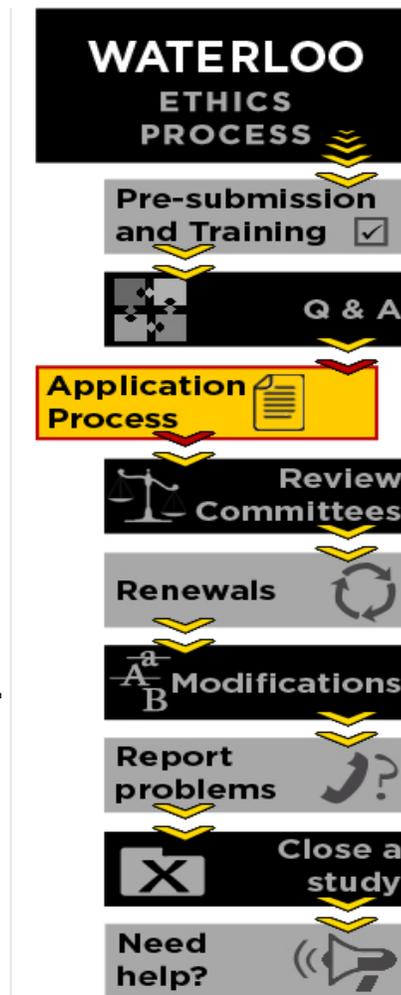
When do researchers need ethics clearance?

- While affiliated with the University of Waterloo - any research that collects data from human participants requires ethics clearance.
- This includes collection of bio-metric data, biological materials (blood, urine, saliva) and responses to any qualitative or quantitative questions (interviews, surveys, focus groups etc.)
- Research (TCPS2 (2014), Article 2.1)
 - “an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation...a determination that research is the intended purpose of the undertaking is key for differentiating activities that require ethics review by an REB and those that do not”
 - Knowledge that is generalizable, outside of uWaterloo.
- Increase in cross-disciplinary research
 - Students not trained in human participant research more often involved in data collection from human participants – may not realize that ethics clearance is required

How to apply for ethics clearance?

- Application process, step by step
- Ethics review and research with human participants must follow the Tri-Council Policy Statement 2 (TCPS-2 2014)
- Samples and templates: Recruitment, Information and consent, feedback and other supporting materia

YouTube Video: How to apply for ethics clearance



What types of activities fall into the Research Category

- Research funded by Tri-Councils (i.e., NSERC, CIHR, SSHRC) or other sponsor grants
- Contract or industrial research
- Research which requires review by the Human or Clinical Research Ethics Committee or Animal Care Committee
- Fourth year theses, Masters theses, PhD dissertations
- Major/Masters research projects
- Post-doctoral research projects
- Applied research/research related to a consulting assignment

Responsible Conduct of research and Research Integrity at UW

Who makes the rules? What's the definition of Research Integrity?

- All Canadian Universities who receive research funds from CIHR, SSHRC, and NSERC are obliged to follow The Tri-Agency Framework: Responsible Conduct of Research (RCR Framework) rules from the Secretariat for the Responsible Conduct of Research (SRCR).
- “Researchers shall strive to follow the **best research practices honestly, accountably, openly and fairly in the search for and in the dissemination of knowledge**. In addition, researchers shall follow the requirements of applicable institutional policies and professional or disciplinary standards and shall comply with applicable laws and regulations”.

(Tri-agency Framework, 2011, p. 3)

Research Integrity and Academic Integrity, what is the difference?

Academic integrity breaches

- Academic integrity breaches affect the student and their learning objectives primarily. (e.g. student cheats on a test)
- Academic only misconduct investigations are handled first at the department and faculty level according to [Policy 71](#) and possibly Policy 33.
- Issues that are not considered to be research misconduct which include faculty and staff are handled through performance management procedures
- Unsure what type(s) of breach you see? [Contact](#) us for help.

Research integrity breaches

- Affect the entire scientific enterprise and the integrity of the scholarly record.
- Potentially affect huge numbers of people's health and well-being, the environment, future funding, the reputation of the university and the careers of researchers.
- Can set back good research-often by years.
- Students who commit research misconduct also commit academic misconduct.
- Must be reported to VP University Research and handled in accordance with [Integrity in Research Administrative Guidelines](#) and [Faculty MOA](#)

What has changed with the implementation of the RCR Framework?

1. Broader list of behaviours considered to be a breach of the RCR Framework.
 - In addition to the traditional Falsification, Fabrication and Plagiarism- a range of other behaviours are considered to be breaches
2. Significant change to required breach reporting process – mandatory centralized reporting to VP University Research, not handled within faculty
3. Supervisor's role in managing breaches has changed- now limited to reporting to VP University research and possibly on advising on sanctions

RCR: Framework Shifts in Scope

- Pre- 2011 – only Fabrication, Falsification and Plagiarism were considered to be a research misconduct or integrity breach.
 - Often the subject of intense media scrutiny and erosion of public trust in research.
 - In the USA and other countries around the world, only these actions are considered to be research ‘misconduct’ or a breach.
 - Depending on where and how the PhD student was trained – s/he may be unaware of Canada’s critical expansion of behaviours considered a research integrity breach as of 2011.
- Since 2011 – Canada’s Tri-Agency Framework, *Responsible Conduct of Research* (RCR): list of behaviours falling within the definition of a RCR breach increased significantly.
 - These often behaviours often overlap with University policies governing Academic Integrity, such as Policy 33 (ethical behaviour), as well as Policy 71 (student discipline) – but come into play when the activity is considered to be ‘research’.

Examples of Breaches to Responsible Conduct of Research (RCR) Framework

1. **Fabrication of data**
2. **Falsification of data**
3. **Plagiarism**
4. Destruction of research records
5. Redundant publications
6. Invalid authorship
7. Inadequate acknowledgment
8. Mismanagement of conflict of interest
9. Misrepresentation in an agency document
10. Mismanagement of grants or awards
11. Breaches of agency policies of requirements/failure to obtain approvals

(Tri-agency Framework: Responsible Conduct of Research, 2011)

Examples of Research Integrity Breaches

– Data and Citations

Fabrication of data: Making up data, source material, methodologies or findings, including graphs and images.

Falsification of data: Manipulating, changing, or omitting data, source material, methodologies or findings, including graphs and images, without acknowledgement and which results in inaccurate findings or conclusions. E.g. Altering figures by “removing outlier values or replacing outliers with mean values to produce results that conform to predictions” (US Office of Research Integrity [case summary](#), 2015).

Plagiarism: Presenting and using another's published or unpublished work, including theories, concepts, data, source material, methodologies or findings, including graphs and images, as one's own, without appropriate referencing and, if required, without permission.



Examples of Research Integrity Breaches:

Responsible authorship

Inadequate acknowledgment: Failure to appropriately recognize contributions of others in a manner consistent with their respective contributions and authorship policies of relevant publications.

Redundant Publications: The re-publication of one's own previously published work or part thereof, or data, in the same or another language, without adequate acknowledgment of the source, or justification

Invalid authorship: Inaccurate attribution of authorship, including attribution of authorship to persons other than those who have contributed sufficiently to take responsibility for the intellectual content, or agreeing to be listed as author to a publication for which one made little or no material contribution.

(Tri-agency Framework: Responsible Conduct of Research, section 3.1 2011)

See 'Should I be listed as an Author' Case study (ORI, 2013)

Examples of Research Integrity Breaches:

Responsible authorship

Authorship disputes are the most common cause of RCR breach allegations.

- Encourage researchers to:
 - Consult journal requirements
 - Negotiate authorship in advance, in writing
 - Re-negotiate authorship as research teams, responsibilities or roles change on a research team.
 - See COPE or ICJME for strong standards
 - Seek intervention before a dispute turns into an allegation (e.g. Office of Human Rights and Conflict Management)

See Negotiating Authorship With Integrity section of our website for resources on authorship.

If conflict arises, researchers are encouraged to visit the Office of Conflict Management and Human Rights before a dispute becomes an RCR breach.

See Academy of Management Best Practices videos.

Examples of Research Integrity Breaches: integrity in administration

Destruction of research records: The destruction of one's own or another's research data or records to specifically avoid the detection of wrongdoing or in contravention of the applicable funding agreement, institutional policy and/or laws, regulations and professional or disciplinary standards

Mismanagement of conflict of interest: Failure to appropriately manage any real, potential or perceived conflict of interest, in accordance with the Institution's policy on conflict of interest in research, preventing one or more of the objectives of the Framework (Section 1.3) from being met .E.g. failing to disclose links to drug companies in off market clinical drug trial (ORI case study, 2013)

Breaches of agency policies of requirements/failure to obtain approvals: including ethics clearance, permits or certifications

Examples of Research Integrity Breaches: Managing Funding

Misrepresentation in an agency document:

- Including provision of incomplete, inaccurate or false information in applications or related documents,
- Holding an agency award when not eligible because of prior breach of responsible conduct of research policies, and/or
- Listing of co-applicants, partners or collaborators without their agreement.

Mismanagement of grants or awards:

- Using funds for purposes inconsistent with the policies of the Agencies.
- Providing incomplete, or inaccurate information on documentation related to expenditures.

(Tri-agency Framework: Responsible Conduct of Research, section 3.1 2011)

Examples of Research Integrity Breaches: Other

Suppression of research results: including, delay in submitting corrections and retractions.

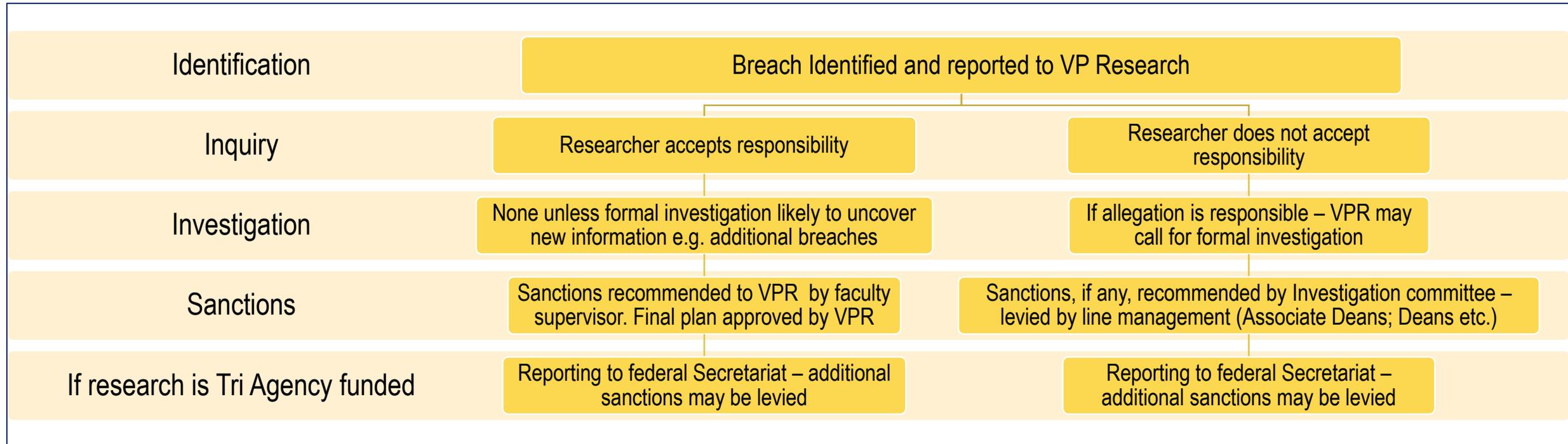
Abuse or coercion of others: including forcing others to commit or be complicit in the knowledge of a research integrity breach.

Required Centralized Reporting Structure

– How does it work?

Since 2011, all allegations must be reported through a centralized ‘arms length’ process.

- **All members of the uW community are required to report a breach or suspected breach to the VP University Research (VPUR) or delegate: uW’s Chief Ethics Officer.**



Breach of RCR Framework: *Responsible Conduct of Research*



Sanctions to Researchers Sanctions to University

Possible Sanctions to Researcher:

- Suspension
- Letter of concern, note on permanent records
- Withdrawal of pending publications
- Withdrawal of research privileges
- Academic sanctions-expulsion, loss of credit
- Leave without pay
- Lost eligibility to apply for future Tri-Agency grants

Possible Sanctions to uWaterloo :

- Repayment of research funding
- Ineligibility for future funding (temporary or permanent)
- Adverse publicity
- Revocation of Canada Research Chair position(s)
- Loss of some or all Tri-Agency funding for the University

What should I do if I suspect a breach to RCR Framework

- Every uW person has an obligation to report suspected breaches to the RCR Framework
- Investigating misconduct:
 - Complete [complaint form](#) and send to VPUR

Tips to avoid conflict and allegations of irresponsible research conduct

- Be clear from the onset about who owns Intellectual property (see our guidelines)
- Resist the temptation to fabricate/falsify data or plagiarize. Ensure you're clear on best practices for your discipline.
- Treat colleagues with respect and negotiate/document your role in every collaborative project.
- Be pristine with your research records. Organize, be consistent and document everything- these documents are critical to verifying process and avoiding issues down the line.

Resources

- From Research Integrity tab on ORE
- Website:
 - *Revised* Article 14 of Memorandum of agreement
 - (faculty)
 - *Revised* Research Integrity Guideline (staff and students)
 - *New* FAQ sheet (complaint requirements)
 - *New* Research Misconduct training (faculty, staff, students – online and free)
 - *New* Video Series The ethics of research and publishing
 - Authorship, plagiarism, slice and dice, journal publications, conference papers and presentations, reporting research, reviewing manuscripts, global ethics in publishing

When in Doubt, give us a Shout!

Responsible Conduct of Research?

Jannet Ann Leggett, JD, Chief Ethics Officer

jaleggett@uwaterloo.ca

Ext. 36005

Research Ethics

Sacha Geer, PhD, Manager, ORE

sacha.geer@uwaterloo.ca

Ext. 37163