## Research Compliance

A refresher





#### **Outline**

- Rationale
- UM Policies
  - Code of Research Ethics
  - Responsible Conduct of Research Policy
  - Investigation Procedures
- Mitigation
- Ethics (human and animal) and Biosafety
- Consequences



#### **The Mandate**

#### Responsible Conduct of Research (RCR)

- In 2016 the federal government, via the Tri-Agencies (CIHR, NSERC, SSHRC), mandated that universities:
  - develop policies and procedures in respect of the responsible conduct of research
  - undertake educational activities regarding RCR
- Breaches involving Tri-Agency funded research are reported to the Secretariat on Responsible Conduct of Research (SRCR)



#### **Code of Research Ethics**

- Defines the expectations for researchers in the context of the responsible conduct of research
- The Code of Research Ethics has several components:
  - academic rigour
  - attribution
  - conflict of interest
  - funding agencies
  - supervision of research
  - code not exhaustive



# Responsible Conduct of Research Policy

- Defines the expectations regarding responsible conduct of research
- Defines
  - · "breach"
  - "designated officer"
  - "investigation"
- Ensures that funding agencies have confidence in research at the UM and that funds allocated to research at UM are used responsibly



#### Reasons for Procedure

- Researchers are expected to conduct Research in accordance with the University's Code of Research Ethics and the Responsible Conduct of Research Policy, and to uphold the following responsibilities:
  - accurate referencing
  - acknowledgment
  - authorship
  - conflict of Interest
  - record keeping
  - rigour



## RCR - Investigation Procedure "Breach"

- means conduct, behaviour, actions or omissions which are inconsistent with or violate the Code of Research Ethics.
- Innocent errors and oversights may constitute a Breach, but intention will be considered in regard to any penalty, discipline or other measures taken following an Investigation.



## RCR - Investigation Procedure "Breach"

- Can include (but not limited to):
  - breach of funding agency policies/requirements
  - conflict of interest and confidentiality policies
  - copyright breach
  - research record mismanagement
  - fabrication or falsification
  - plagiarism
  - inadequate acknowledgement
  - invalid authorship
  - Inaccurate information on funding applications



#### "Designated Officer"

- The person to whom breaches must be reported
- At UM, this is the Vice-President (Research and International)
- Responsible for the initial review of the allegation
- Decides (within 15 working days of receipt of an alleged breach) whether the disclosure was made in good faith and requires investigation or was frivolous or vexatious.



#### "Investigation Committee"

- A minimum of three individuals, one of whom must be a community (lay) representative. The Chair of this committee will be identified by the Designated Officer from among this group.
- Can add additional representatives if the allegation involves a graduate student, post-doctoral fellow, research associate, etc.
- Majority of the committee must be UMFA members (including academic administrators)



- The researcher alleged to have breached the policy is entitled to representation by the appropriate bargaining unit or other person of their choosing
- They will have the opportunity to address the allegations
- Investigations will normally be completed within 90 days however extensions may be granted by the Designated Officer
- All investigations are conducted in compliance with the principles of procedural fairness and natural justice as well as any existing collective agreements



# RCR - Investigation Procedure Discipline

 If the finding of the Investigation Committee is that a breach occurred and if all appeals have been exhausted, then the Designated Officer, the Provost and Vice-President Academic, and the appropriate Dean/Director/Unit Head will meet and determine any disciplinary action(s)



#### Consequences

- UM disciplinary actions as per any collective agreements in place
- If the breach involves Tri-Agency funded research, the breach is reported to the SRCR which then reports it to the relevant Tri-Agency, that may enact their own disciplinary actions, which may include prohibition from applying to the Tri-Agencies for a period of time or never as well as not serving as reviewer or on review panel.
- This discipline is separate from and in addition to, any university discipline that may be applied.



### **Mitigation**

#### **FAAF**

- The Funding Application Approval Form (FAAF) form – ensures that Department Heads, Deans/Directors, and ORS staff are aware of and sign off on, research applications
- PI is responsible for the accuracy of FAAF
- ORS ensures that all required compliance approvals are, or will be, in place at the time funds are awarded and expanded
- Determines where the research will be conducted



## Mitigation (cont'd) FAAF

Please note the new wording on this form:

"Submitting inaccurate or false information in these forms <u>IS</u> a breach of the University of Manitoba Responsible Conduct of Research Policy."



## Mitigation (cont'd)

#### **FAAF**

- MUST declare ALL <u>financial conflicts of interest</u> income from other universities, industries, or sponsors
- MUST declare all <u>appointments</u> at other educational institutions, industries, or sponsors – world wide



## Mitigation (cont'd)

#### **Research Integrity Online**

- Purchased from Oxford University Press
- Available free for UM faculty, staff and students
- 4-5 hours to complete
- Covers the most common pitfalls that researchers can face



## Mitigation (cont'd)

#### **iThenticate**

- Plagiarism detection software for research-related publications
- For faculty and graduate student use
- Person submitting document to iThenticate MUST be an author or co-author
- Strongly recommended for all research proposals, draft manuscripts, theses and final manuscripts ready for submission



#### **Human Ethics**

- Must first complete the Tri-Agency C.O.R.E. course online (Course on Research Ethics)
- Submit protocol to the appropriate ethics office:
  - Shelly Rempel-Rossum (Bannatyne), or
  - Pinar Eskicioglu (Ft. Garry)



#### **Human Ethics**

- Will be reviewed by a REB
  - Bannatyne Campus (2 of)
  - Ft. Garry Campus (3 of)
- Projects can be monitored post-approval on a risk basis with higher risk projects receiving more monitoring.
- A full audit may occur if there are adverse events, problems or if the project is very high risk.
- NB: Any work involving human participants <u>even if conducted in</u> <u>another country</u> – requires REB review and approval.
- If a UM researcher is involved, the same requirements apply to research at all locations including in outer space.
- Research involving animals requires animal ethics approval.



#### **Human Ethics**

#### Consent (ICF)

- May only do what is explicitly stated on the Consent Form with respect to:
  - procedure
  - data storage, handling, transfer
  - etc.
- Cannot deviate unless an amendment to ethics is obtained and participants reconsent (if applicable)



#### **Animal Ethics**

- Must first complete the Animal User Training Course
- Submit protocol to the animal ethics coordinator, Tracy van Osch
- Reviewed by Animal Care Committees (Ft. Garry and Bannatyne campuses)



#### **Animal Ethics**

- Post-approval monitoring by vet staff and/or animal health technicians.
- UM subject to periodic inspection/site visits by the Canadian Council on Animal Care (CCAC)



### **Biosafety**

- Research programs now receive certification from the Biosafety Office (Steve Cole)
- Once program approval is obtained, and as long as the risk group agents do not change, certification is maintained
- Subject to periodic lab inspection by the staff of the biosafety office (EHSO)



# **Breach Penalties** (from SRCR files)

Breach	Agency Penalty
Fabrication	<ul><li>terminated grant</li><li>ineligible to apply for 5 years</li></ul>
Plagiarism	<ul><li>terminated grant</li><li>ineligible to apply/hold for life</li></ul>
Misrepresentation in application	ineligible to apply for 2 years
Mismanagement of funds	<ul> <li>repay ineligible expenses</li> <li>terminated grant</li> <li>ineligible to apply/hold for life</li> </ul>
Failure to comply with Agency policies	<ul><li>terminated grant</li><li>ineligible to apply/hold for 3 years</li></ul>



