

RCR AND REBS RESPECTIVE ROLES AND RESPONSIBILITIES (PART 2)

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2 ROLES AND RESPONSIBILITIES DIRECTOR, UOTTAWA OREI

RCR

- Receive Allegations and ensure that the processes for addressing Allegations, are completed in accordance with [Procedure 29-2](#)
- Consultation and education regarding Responsible Conduct of Research.
- Provide reports on the status and outcome of Inquiries and Investigations into an alleged Breach of RCR to the appropriate bodies
- Policy development & implementation

REBS

- Manage the REB Office
- Manage REB membership (recruitment, ensure appropriate representation)
- Oversee / provide education to REB members, research community, staff
- Policy development & implementation

RESEARCHER RESPONSIBILITIES

RCR Framework (Article 2.1.2)

Follow best research practices honestly, accountably, openly and fairly

Follow institutional policies & professional or disciplinary standards

Comply with applicable laws and regulations

TCPS 2

Be knowledgeable about TCPS 2 guidance

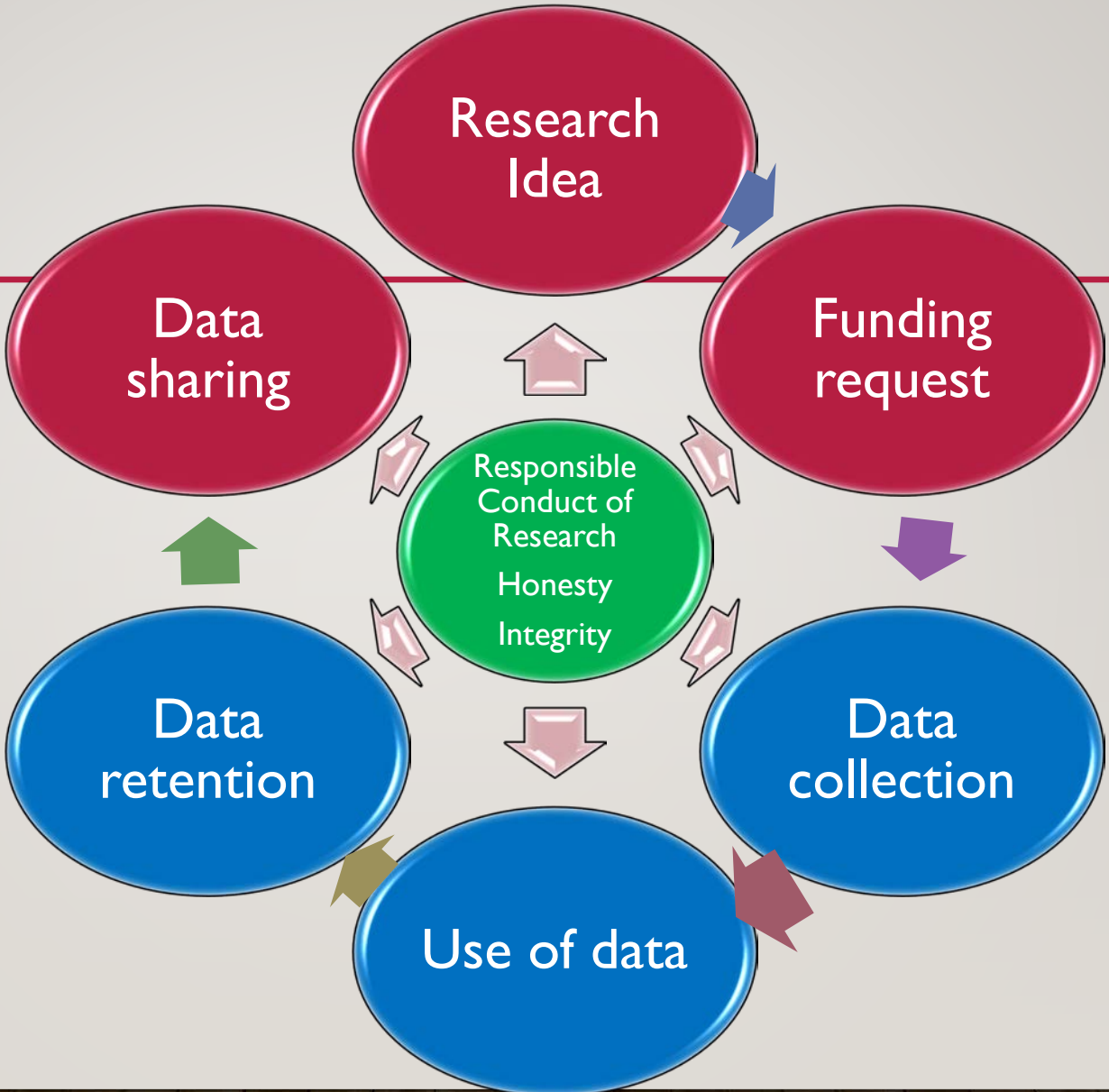
Apply this guidance to the design and conduct of their research

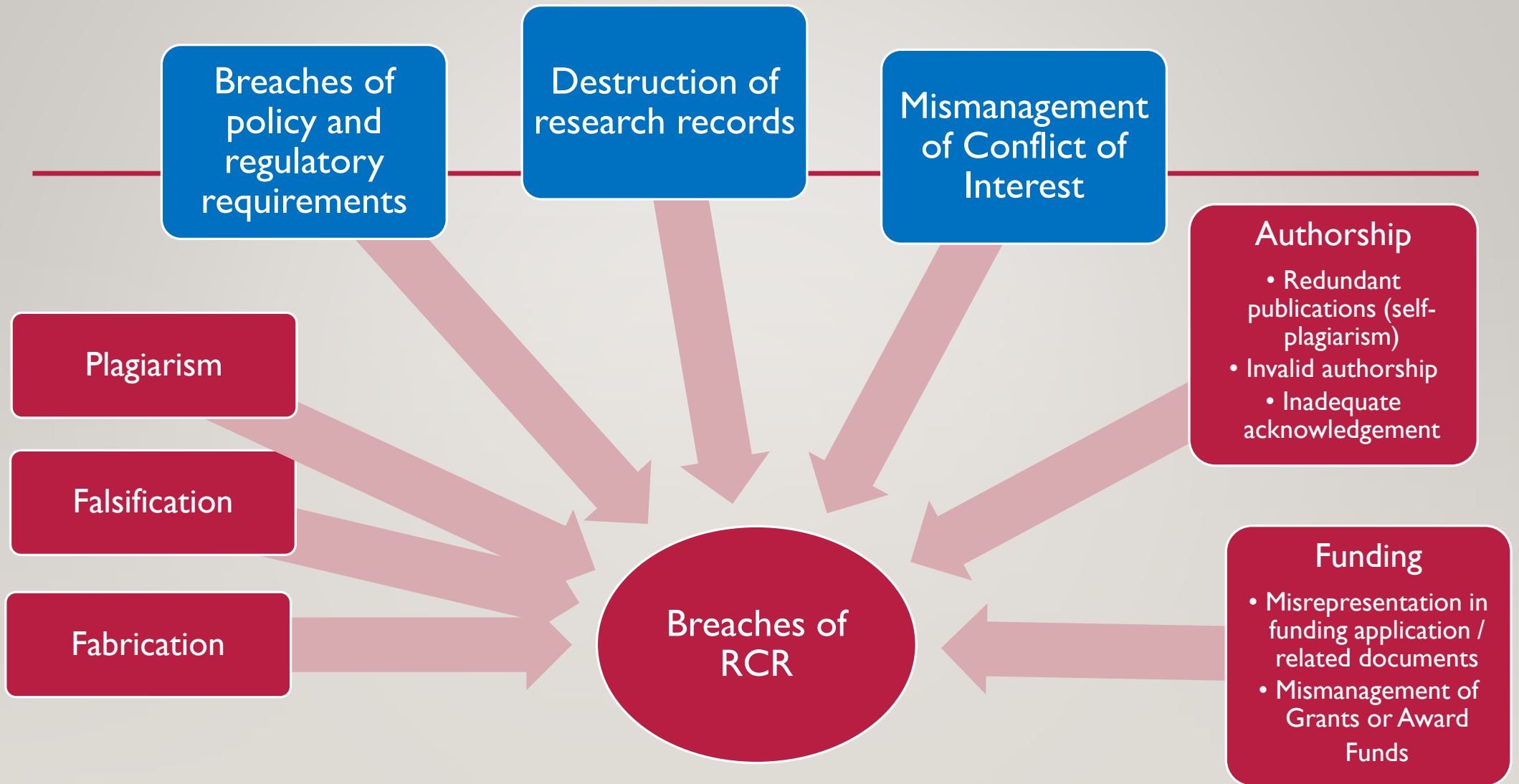
Ensure that all team members are trained to conduct ethically acceptable research

Be aware of their professional and other institutional responsibilities

Be aware of their legal obligations in the conduct of their research

Where
REB and RCR
intersect





DETAILS – BREACHES

- **3.1.1 Breach of Tri-Agency Research Integrity Policy**
- C) 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.
- H) Mismanagement of conflict of interest: Failure to appropriately identify and address 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 RCR Framework (Article 1.3) from being met.
- **3.1.4 Breach of Agency Policies or Requirements for Certain Types of Research**
- Failing to meet Agency policy requirements or, to comply with relevant policies, laws or regulations, for the conduct of certain types of research activities; failing to obtain appropriate approvals, permits or certifications before conducting these activities.

WHAT TYPES OF POTENTIAL BREACHES MAY THE REB RECEIVE OR NOTICE?

- Your experience:
- Other
 - REB may be contacted for confirmation that a project has received REB approval
 - REB could detect issues around renewals of certificates, approval of modifications
 - Participant complaints

IMPORTANT TO KEEP IN MIND

AUTHORITY AND INDEPENDENCE OF THE REB

- Article 6.2 “Institutional policies and procedures shall also support and promote the independence of REBs in their decision making so that REBs may be free of inappropriate influence, including situations of real, potential or perceived conflicts of interest (see [Chapter 7](#)).”
- Article 6.3 The institution shall grant the REB the mandate to review the ethical acceptability of research on behalf of the institution, **including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans**. This mandate shall apply to research conducted under the auspices or within the jurisdiction of the institution, using the considerations set forth in this Policy.
- **Application** Institutions shall respect the authority delegated to the REB. An institution may not override an REB decision to reject a research proposal. An appeal of the REB decision to reject a research proposal can only be brought in accordance with Section C of this chapter.
- An REB approval applies to the ethical acceptability of the research, and does not, in itself, constitute authorization for the research to proceed.

SCENARIO I

- The REB receives a complaint from a participant that he was harmed during a research procedure. He believes that the researcher is not adhering to the study protocol.
- What are the responsibilities of the REB?
- What actions should the REB take?
- Should this be forwarded to the RCR contact?
 - Does the participant want to make an Breach of RCR complaint?
 - If yes, would have to go to RCR contact immediately
 - If no, may not need to go to RCR contact immediately

SHOULD APPROVAL BE PUT ON HOLD? WHAT STEPS SHOULD THE REB TAKE TO DETERMINE THIS?

- Obtain information from participant in writing (what happened; where; when etc.)
- Ask participant if researcher was informed of the harm
- Check if researcher submitted adverse events report
- Inform researcher of the complaint (whether formal or not)

- Could be done before getting in touch with RCR contact or concurrently – safety of participants is first concern
 - REB or RCR contact may need to get in touch with other groups / services (e.g., risk management)

SCENARIO 2

- An REB manager is contacted by a Vice-Dean to confirm that a study conducted by a PhD student has obtained REB approval.
- This question was raised by a member of the thesis review committee, who stated that the research conducted seemed to fall under TCPS 2 and therefore should have obtained REB approval.
- The REB manager checks, and there is no record of the project being submitted to the REB for approval; there is no record of any file under the student's name; no similar title with the supervisor.
 - This may be an RCR issue but a determination needs to be made regarding the need for REB review

NEXT STEPS?

- What would happen at your institution?

UOTTAWA RCR PROCEDURE

- **7. Role of the Office of Research Ethics and Integrity:** Throughout the process for addressing an Allegation, the Director of the Office of Research Ethics and Integrity shall **coordinate** with the Appropriate Authority and any other relevant authorities within the University, to assure that the processes set out in this Procedure are conducted in a timely manner and in compliance with Research Sponsors' Policies and/or Requirements; and shall act as the University's institutional **liaison** with the Research Sponsors, the Agencies, the Secretariat on Responsible Conduct of Research, as well as the University's **Research Ethics Board** and any other parties, as may be required.

UOTTAWA RCR PROCEDURE

- 16. The Appropriate Authority will acknowledge receipt of the Allegation to the Complainant, with a copy to the Director, Office of Research Ethics and Integrity, inform the Complainant of the procedural steps for responding to the Allegation (if the identity of the Complainant is known) and, in consultation with the Director, Office of Research Ethics and Integrity **or such others as the Appropriate Authority considers necessary**, review the Allegation and if necessary and if the identity of the Complainant is known, seek clarification from the Complainant on the information contained in the Allegation.
- 20. The Appropriate Authority determines the following, in consultation with the Director, Office of Research Ethics and Integrity, **or such others as the Appropriate Authority considers necessary**, based on the information received in the Allegation and in the Response: