

# REB Role in RCR Allegations Involving TCPS2



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**PANEL ON RESPONSIBLE  
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REBs and institutional officials responsible for RCR matters may each have responsibilities when an alleged breach of TCPS 2 is received.

The Secretariat has heard that:

- sometimes their activities overlap
- sometimes the division of responsibilities isn't clear



## Objectives

- Provide a brief overview of the RCR Framework and a typical RCR process
- Describe the roles that REBs may play in an RCR process
- Describe some challenges and common questions that may arise when an RCR allegation involves TCPS 2
- Foster discussion through scenarios and quiz questions

## What is the Tri-Agency Framework: Responsible Conduct of Research (RCR Framework) ?

- Joint document of the three federal research agencies
- Describes responsibilities of researchers, institutions and Agencies
- Defines breaches of the RCR Framework
- Sets out the process that the Institutions and Agencies follow for addressing allegations of breaches of Agency policies

## Breaches of the RCR Framework

- Examples of breaches include plagiarism, falsification, fabrication, inappropriate authorship, financial mismanagement, and more
- They also include breaches of Agency policies, such as TCPS 2
- A breach of TCPS 2 is a breach of the RCR Framework.

# Overview of a Typical RCR Process

1. Complainant or REB submits an allegation to the RCR contact
2. Institution conducts an RCR inquiry to determine whether
  - the allegation is responsible
  - an investigation is required
3. If needed, the institution convenes an investigation committee
  - expertise relevant to the allegation
  - no COI with respect to the allegation
  - includes at least one member external to the institution



## Typical RCR process (cont.)

### 4. Investigation Committee:

- identifies the facts related to the allegation
- makes a finding – did a breach of policy occur?

### 5. Institution:

- receives the report, seeking clarification if needed
- determines what actions to take in response to the committee report



## Where does the REB fit into an RCR process?



Possibilities include:

- submit an allegation or advise complainants to do so
- answer questions during the inquiry or investigation
- after the process is over, REB role will vary
  - provide advice to the institution upon request
  - carry out its mandate in response to information it receives



## What should REBs (and admins) not do?

- participate as investigation committee members when the allegation involves research reviewed by their REB



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## REB Carries Out Its Mandate

- approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans (TCPS 2, 6.3)
- providing a fair hearing to the researchers involved, and provide reasoned and appropriately documented opinions and decisions. (6.13)
- providing prompt reconsideration of decisions affecting a research project. (6.18)



## Sample Scenario - Active Research

The REB discovers that a researcher is currently carrying out research involving interviews with human participants but isn't using the consent process previously approved by the REB.

Possible steps to follow...

# Sample scenario – Active Research – Possible Steps

## 1. REB

- decides whether to suspend or terminate its approval of the research, and
- forwards an allegation and pertinent info to the RCR contact

## 2. Institution

- arranges for an inquiry, and possibly investigation
  - may ask the REB to provide information or answer questions

# Sample scenario – Active Research – Steps (Cont.)

## 3. Institution

- a) if a breach is confirmed, determines actions to take in response,
  - sanctions against researcher (if applicable)
  - actions to remedy breach and protect participants (sometimes)
- b) may inform affected parties of relevant findings
  - the institution's disclosures will be guided by legislation, collective agreement, etc.

## 4. REB

- a) carries out additional actions within its mandate in response to information received from the institution (if any)
- b) provides advice to the Institution upon request

## Common Question #1 - Should the REB resolve the problem? Forward the matter to RCR? Both?

- **A judgement call**
- Our suggestion: the REB could address the problem on its own, without submitting an RCR allegation, when:
  - the issue is related to TCPS 2,
  - the impact on participants is minimal, and
  - the issue is clear and straightforward to resolve.
    - example: overdue report

## Forward the matter to RCR? (Cont.)

Forward the allegation to the RCR contact if:

- the problem is persistent (e.g. annual report not submitted, even after being reminded),
- the impact on participants is greater than minimal, or
- the issues are serious or in dispute.

**When in doubt, confer with the RCR contact.**





## Common question #2 – Handling Overlap

- Secretariat has received concerns that REBs and RCR committees duplicate each other's work,
  - E.g., an RCR investigation committee re-interviewing people that an REB has already spoken to.
- sometimes unnecessary, but sometimes appropriate – different perspectives

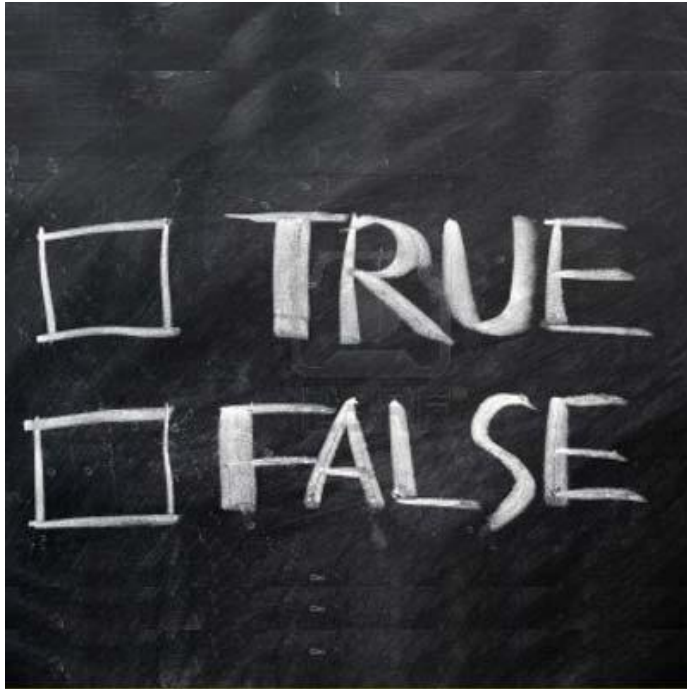
**Talk to the RCR contact to determine how best to optimize efforts**

# Summary

When an allegation related to TCPS 2 is received:

- REBs determine whether the research should continue or be suspended, and whether to forward to RCR
- RCR process determines whether a breach occurred
- If a breach is confirmed:
  - Institution is primarily responsible for determining next steps
  - REB role may vary according to circumstances
- Every case is different
- When questions arise, communicate with the RCR Contact

## Quiz Question #1



True or False?

It is the REB that determines whether or not the researcher breached TCPS 2, and therefore, the RCR Framework.

## Quiz Question #1 - Response

False

The RCR process determines whether the respondent committed a breach.

The REB's decisions relate to approval, modification, or termination of the research itself.



## Quiz Question #2

### Scenario

- An REB has terminated its approval because of evidence that 10 participants were interviewed without informed consent.
- The REB forwarded the allegation to the RCR contact.
- A breach was confirmed

## Quiz Question #2 (Cont.)

**After a breach related to TCPS 2 is confirmed, who decides the following - the Institution or the REB?**

- whether to impose sanctions against the researcher?
- whether to require the researcher to get more training?
- what to do with the data from those 10 interviews?
- what to communicate to participants and how?
- whether to assess the researcher's compliance in his/her other REB-approved activities ?



**Thank you!**

We hope to use your feedback to develop an interpretation or educational materials.

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# Questions?



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### **3. Continuing research ethics review: What if a researcher does not submit an annual report to the REB and continues to conduct research in the absence of a renewal of REB approval? *Revised February 2016***

The researcher's failure to submit an annual status report means that the researcher would not be in compliance with TCPS 2 requirements regarding continuing ethics review ([Article 6.14](#)). At the time of its initial review of research, an REB determines the frequency of continuing ethics review (Article 6.14) and communicates it to the researcher. While an institution may put in place a system for notifying its researchers that their ethics approval is about to expire, it is the researcher's responsibility to maintain ethics approval for his/her study throughout the life of the project.

If the researcher has been notified that ethics approval for a study will expire by a certain date and fails to submit a report by the specified date, the REB has the authority to terminate its approval of the ethical acceptability of the research ([Article 6.3](#)). The REB should notify the institution of its decision to terminate its approval. It is up to the institution to determine how it will proceed to ensure the non-compliant research is either brought into compliance or is stopped. The ultimate responsibility for ensuring compliance with TCPS 2 rests with the institution by virtue of having signed the [Agreement on the Administration of Agency Grants and Awards by Research Institutions](#) with the Agencies.

### **4. Continuing research ethics review: What if a researcher obtains ethics approval but the research procedure deviates from the approved proposal, and the researcher does not seek ethics approval for the modification?**

If the change to research is a necessary reaction to an unanticipated event [Article 6.15](#) would apply. If the change is a result of a researcher's planned deviation from the original study [Article 6.16](#) would apply. In either case, the nature of the departure from the approved research will determine when the researcher should have informed the REB or sought renewed research ethics approval. In both cases, if earlier notification was required and the date of the unanticipated issue report or the request for change has passed, the researcher would be conducting research not in compliance with TCPS 2. The REB may formally notify the researcher and the institution that its approval for the research is suspended or revoked and may investigate whether the level of risk to participants was altered or increased as a result of the unreported change. It is up to the institution to act to ensure that the non-compliant research does not proceed.