

## Research Privacy Breaches

### Purpose

This guidance was developed to provide clarity around process and specific considerations for Privacy breaches involving research participants in research settings.

### Background

Privacy breaches occurring within clinical research settings are connected, but distinct from privacy breaches occurring outside research settings. Participation in research is voluntary, which needs to be accounted for in the risk/benefit assessment of any breach. This voluntary nature of participation is also usually supported by a signed consent form. Further, consistent across research ethics standards and regulations, researchers have a duty to inform participants in a timely manner if new information becomes available which may impact their willingness to continue participating.

### Steps

1. **Contain** the breach immediately
2. Study team to **analyse** the situation as per below
3. **Inform** the participant unless justification to do otherwise
4. **Report**
  - a. To BC Cancer REB in RISE following [protocol deviation instructions](#)
  - b. **And** to PHSA Privacy following the [instructions on POD](#)

### Assessment of Breach

- Is the patient a research participant? Is the incident related to research activities?
- Is the data breach internal or external to PHSA?
- Any reason not to notify the participant of the breach?
- Reasons to delay notification? (ie. Patient special circumstance, In-patient status, current distress)

### Contacts

BC Cancer Research Ethics Office [reb@bccancer.bc.ca](mailto:reb@bccancer.bc.ca)

PHSA Privacy [privacy@phsa.ca](mailto:privacy@phsa.ca)

PHSA Research Privacy [holly.longstaff@phsa.ca](mailto:holly.longstaff@phsa.ca)

### Resources

PHSA Research Privacy [guidance and instructions](#)

PHSA Privacy Breach reporting instructions on [POD](#)

UBC Clinical REB guidance on reporting [protocol deviations](#)