

Ethics (and Reproducibility)

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BIG DATA





Digital data

Research data

**Human participant
data**



- TCPS2 (and the Principles of Digital Data Management) applies to all funded & unfunded research conducted by institutions that receive federal research funds.
- Research must also comply with institutional policy, federal and provincial legislation (FOIPP & health information) and professional codes and community practices.

TCPS2, which is referenced in *Principles of Digital Data Management*, requires ethics review of all **research** involving

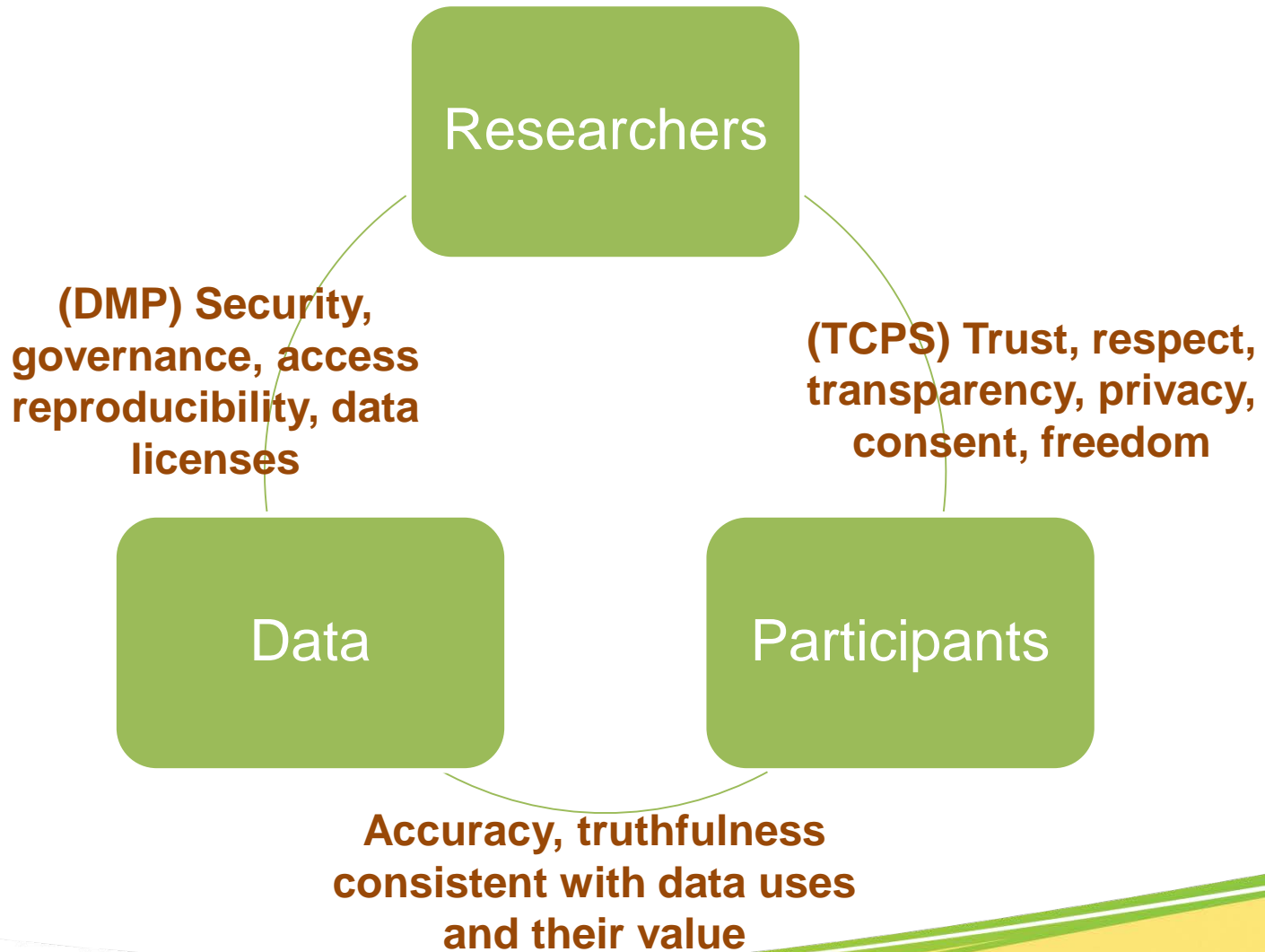
- **living human participants**, their data, and/or responses from participants to interventions, stimuli or questions by the researcher;
- **human biological materials**, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells, including materials derived from living and deceased individuals (if identifiable)

TCPS2 specifically addresses privacy risks at all stages in the research lifecycle (Ch 5) as well as the risks associated with data linkage and re-identification.

TCPS2 also applies when using data originally collected for other purposes (ie health or student records) unless the data are anonymous (**never** had identifiers).

If you don't know how the data will be used.....





DMPs help researchers and REBs address and resolve ethical issues throughout the research lifecycle.

Tools to mitigate ethical concerns while enabling data sharing include

- Unrestricted, tiered consent
- Staged/step-wise approval
- Secondary use with further ethics approval



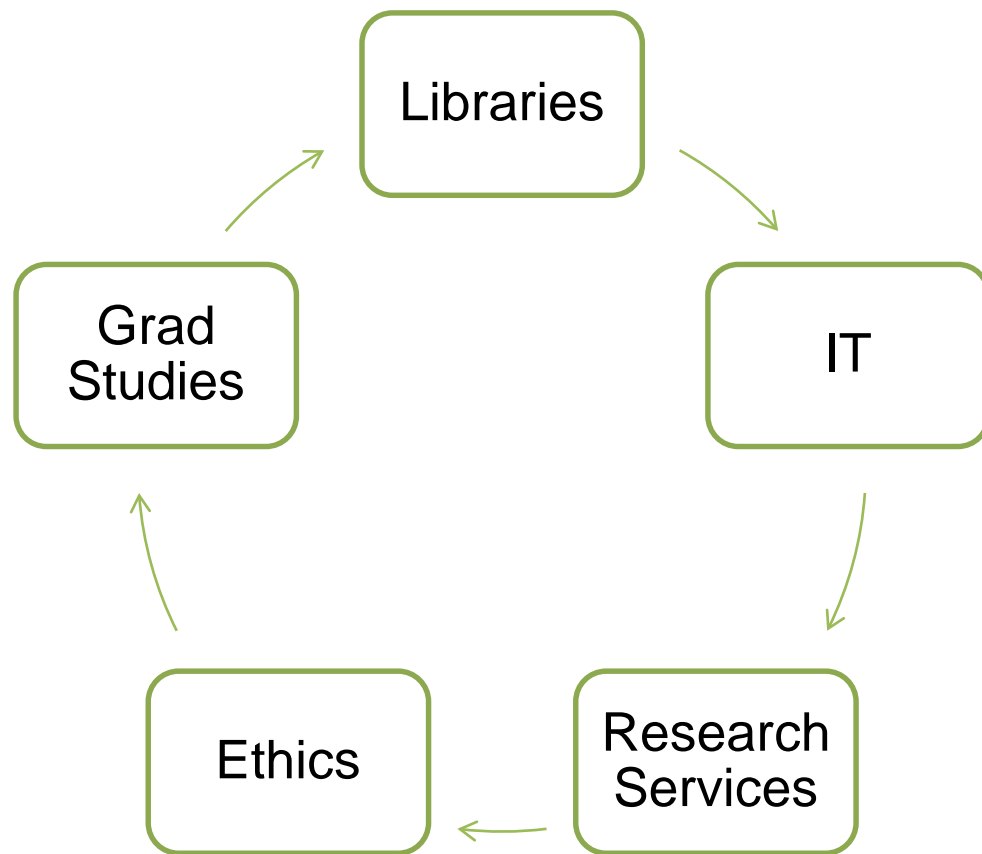


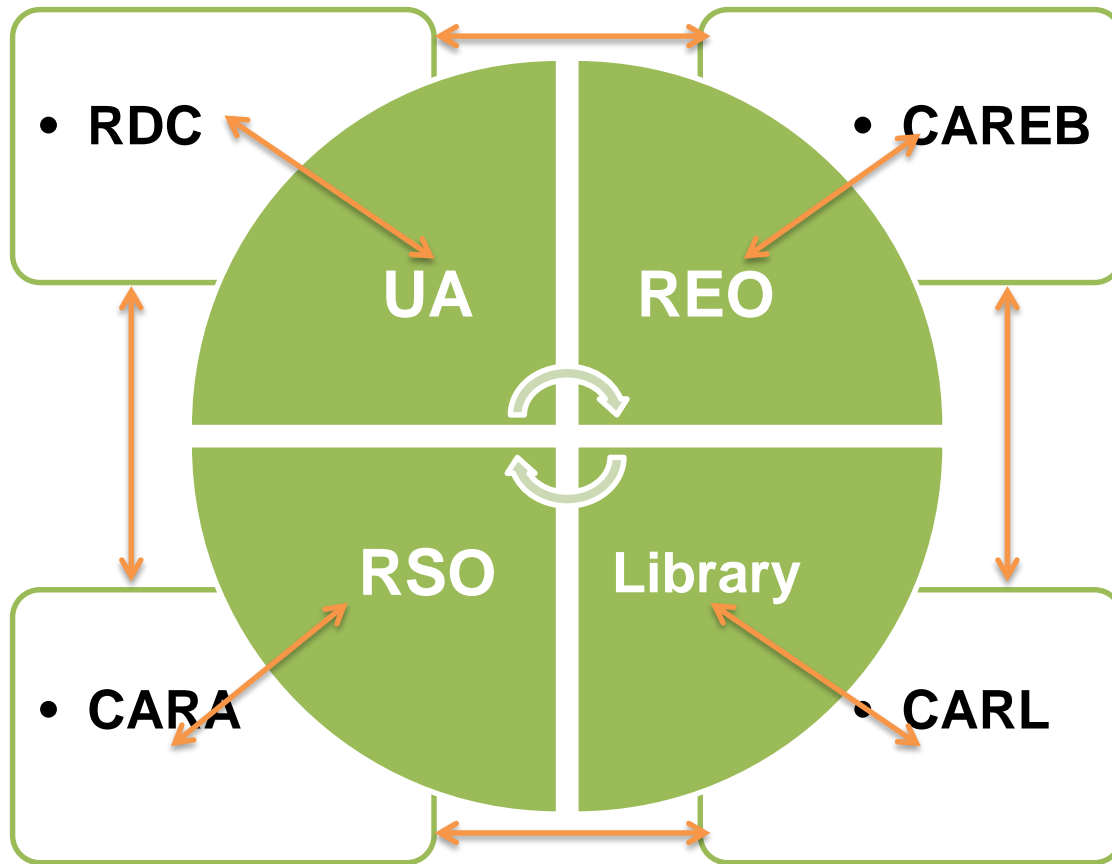
- Data licenses and deposit agreements
- Data linkage – banned or under specific conditions
- Terms for preservation and stewardship should be addressed in the data collection & consent processes which might form part of the metadata
- Registration or certification of secure data repositories

Accelerating change, complexity and competition for scarce resources make even more important that we rely on a principles-based approach to conduct, and to be seen to conduct, good, ethical research. Policies confirm our commitment to uphold these principles.



- Since 1998, universities have operationalized and managed human participant research ethics requirements through various policies, procedures and business practices.
- Our management of research ethics requirements provides a model for how we might approach research data management.
- Research data management, like research, needs an integrated institutional response





Chuck Humphrey – University of Alberta & Portage Research Data Management, has co-authored and co-presented much of this material with me.

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