ECHO for Clinical Research Professionals (CRP) – Summary of (i) Key presentation and (ii) Problem discussion from session held on 25 April 2025

(i) KEY PRESENTATION

Protecting participants – by Jasmine Grant M.ED, HBHSc, CCRP (slides attached)

This was an overview of the regulatory basis for protecting participants and, specifically, their personal health information (PHI), what is required in terms of good research management practice, and what can be done to mitigate privacy breaches.

PHI applies to living or deceased individuals, can be oral or in recorded form, and includes identifiers such as names, addresses, health numbers.

The regulatory framework includes the tri-council policy statement, the Canadian federal *Personal Information Protection and Electronic Documents Act* (PIPEDA) and provincial regulations (e.g. *Personal Health Information Protection Act* or PHIPA in Ontario). In the USA, the relevant legislation is the *Health Insurance Portability and Accountability Act (HIPAA).*

Research staff should complete *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022)*[1] or TCPS2 core training for privacy and protection compliance, review provincial privacy laws specific to one's jurisdiction, and review institutional standard operating procedures and policies for sharing information with external stakeholders.

Staff are responsible to maintain patient rights and privacy, exercise extra caution when sharing with external stakeholders, and assume the role of information custodian.

Safety events (formerly called incidents) are unexpected, unusual or unplanned events and include near-misses that could affect patients, visitors, or staff. Privacy events can be also safety events and must be documented and reported. Events are classified by severity—minor, moderate, severe, and critical—and should be escalated to management in accordance with standard operating procedures.

The potential consequences of these events cannot be underestimated and include loss of trust from participants, legal consequences, employment impacts on particpiants, emotional and mental health harm, risk of identity theft, social harm and stigmatization, damage to researcher-participant relationships and impact on research project integrity.

With regard to privacy breaches of PHI, this is any action resulting in the inappropriate collection , use or disclosure of PHI, including when PHI is lost or stolen e.g., source documents not properly de-identified before sharing with sponsors, including PHI in email communications with sponsors, lost or misplaced medical/research charts, inappropriate disclosure in electronic data capture system queries, using unauthorized identifiers not approved by the REB, and improper disclosure in specimens, questionnaires, diaries, registration forms, or case report forms.

[1] https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html Note: Chapter 5 of the TCPS-2 covers privacy and confidentiality.

Tips to mitigate privacy breaches were presented (see slide below):

A list of resources can also be found on the last slide of the presentation:

(ii) PROBLEM PRESENTATION

Brief Description of the Situation/Scenario:

A double-blinded study has been conducted in which the coordinator was assigned multiple roles including:

- Serving as an unblinded pharmacy technician;
- Performing data entry for adverse events;
- Submitting safety reports;
- Answering queries; and
- Making corrections to source documents.

The main concern was whether it was appropriate for an unblinded person to handle safety-related data and documentation. The situation resolved when the coordinator left for unrelated reasons, and it was addressed with a note to file submitted to the Research Ethics Board. The study was primarily lab-focused with 80% lab-based endpoints, which reduced potential bias concerns.

RECOMMENDATIONS

Recommendations included:

- Use REDCap for data collection to maintain some level of blinding so even though staff know participant gropus while providing REDCap links, they are not directly collecting data.
- Automate data-entry to reduce manual input.
- Limit certain data points to blinded staff only.
- New rule: in the future, no dual blinded/unblinded roles.
- Update risk management log.
- Submit note-to-file to REB.
- Acknowledge reality of resource and/or experience limitations, and multiple-role assignments.
- Amend protocol.
- Note implications for study design classification.