Cohort in Primary Care (COPRI)

2. Research Ethics and Participant recruitment

Cohorte en soins primaires
Cohort in primary care

History: Declaration of Helsinki

- Statement of ethical principles to guide physicians and participants in clinical research involving *human subjects* from the World Medical Association
    - Goal: to prevent mistreatment of human subjects
- Drew inspiration from Nuremberg Code
    - Developed in response to German doctors' medical experimentation on concentration camp victims during WWII
- Physicians involved in clinical research *must* act in participants' best interest
- Bolstered consent requirements
- Includes ethical management of data obtained from human subjects

Tri-Council Policy Statement

- Created jointly between CIHR, NSERC, and SSHRC
- Expresses above Agencies' commitment to people of Canada to promote ethical conduct of research involving humans
- Includes:
    - Ethics Framework;
    - Consent Process;
    - Fairness and Equity in Research Participation;
    - Multi-Jurisdictional Research;
    - Research Involving the First Nations, Inuit, and Métis Peoples of Canada, etc.

Informed Consent

- Purpose: to inform research participants of study details, including expected outcomes, as well as benefits and drawbacks of participation

- Three major elements:
    - Disclosure of information
    - Competency of patient/surrogate to make a decision
    - Voluntary nature of decision

Recruitment

- Will vary according to each individual GMF-U site
- Generally:
    - Adult patients will be approached at random by research assistants in the clinic's waiting room
    - RAs will introduce the topic of the research and ask if the patient is interested in participating
    - If they are interested, RAs will go over the ICF with them at that moment
    - In the case that participants need more time to think about it, RAs can ask for their contact information (Full name, email, phone number) and offer to re-contact them later
    - If the participants are still interested, they can sign the ICF right away and the recruitment is done!
    - See "Cohort in Primary Care study protocol" for more detailed recruitment strategies

Potential Benefits for Participants

- No direct benefits to research participants

- However, their contribution to the study will:
    - Assist in the advancement of knowledge
    - Ultimately support the improvement of primary care services

Potential Drawbacks for Participants

- Possible breach of confidentiality
    - Use of personal/health information by a third party

Suggested Readings

- Cohort in Primary Care study protocol
- Declaration of Helsinki
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Human

Next Steps

- Part 3: RA Positions