Application for a: Reintegration Scheme NEWFELPRO Fellowship for senior researcher Proposal Acronym: **IMPACT** Proposal Title: IMPACT (IMProving Access to Clinical Trials data); observatory of ongoing transition in clinical research regarding data sharing; opportunities and barriers Research area(s): Life sciences LIF Research sub-disciplines: research managements; bioethics- medical ethics; bioinformatics; innovation, research and development; Internet, database systems and libraries; clinical research; knowledge translation Category of research: applied 24 Duration in months: Keywords: clinical trial data sharing, transparency of clinical research, transition, obeservatory, ethics, policies of funders, journals, industry, regulators; perceptions, researchers; knowledge translation Background Abstract: Sharing of clinical trial (CT) data has scientific, ethical, health, and economic value. As current data sharing is insufficient, multiple initiatives have begun to explore possibilities for improvement. This has triggered a transition of clinical research regrading data sharing, which offers an ideal opportunity for natural experiment observatory. Goal Set an observatory to study ongoing transition of clinical research to identify and analyse - tendencies of transition - roles and dynamics of different players - barriers, gaps and opportunities of opening CT data and making them available for further research - change of culture regarding data sharing and research using existing data.

Methodology

- extract relevant policies from websites of funders, journals, pharma, and regulators
- scoping review and survey of researchers
- map changes of characteristics of data repositories

Results will be made publicly available (Internet) to inform the transition process.

Does this proposal possess any of the sensitive ethical issues detailed in ethical issues table?

No