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Clinical Rheumatology Research in the Digital Age: Consent, and Governance Challenges

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Objectives: Canadian rheumatology clinicians are beginning to explore the issues of how data collected in electronic medical records can be used for quality improvement (QI), with the potential for data to be shared across several investigators, and ultimately used for clinical research. As clinicians incrementally move from clinical practice to research they experience difficulty distinguishing between QI and research activities. For example, a lack of guidance exists for patient consent in two areas: 1) electronic consent (e-consent) as patients provide self-reported clinical data electronically (tablets in physician office, online portals), 2) consent for the use of clinical data for research purpose. Presentation findings from the recent Canadian Association of Research Ethics Boards conference revealed clinicians experience difficulty determining what they are ethically permitted to do with clinical data and REB's are having difficulty distinguishing whether QI protocols submitted require review, since QI resides outside the domain of REB review. On this basis, a survey of literature was conducted to identify knowledge gaps and future directions

Methods: Established e-consent and electronic governance search terms were applied to English language articles from: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations (1946- 2012). CINAHL, Embase (1974-2012). Exclusion criteria: non-electronic articles, abstracts and meeting summaries. The initial search yielded 263390 citations. Combined search terms narrowed results to 379. After limiting articles to 2007-2012 and removing duplicates 83 remained, with 8 articles selected for review.

Results: Themes identified include: 1) Patient Privacy-Protection. 2) Consent-Integration, incorporating clinical care and research into the informed consent process, to satisfy ethical requirements for minimal risk studies. 2) Provision to opt out of study. 3) Governance-Authenticity, clinicians indicating consent conditions are met before accessing data. 4) Governance-Auditability, creating transparency within the research process for REB’s.

Conclusion: Despite evidence in the literature that clinical data has been successfully implemented for research under certain conditions, our experience and feedback gained from the ethics community suggests that a large need still exists for clinicians and REB's to gain knowledge on how electronic clinical data can be used for research. Possible implementation challenges occur when attempting to use clinical data for research purposes, it becomes apparent that consent, governance, and compliance requirements will need to change as requirements suitable in a clinical setting are not appropriate for research. Further work is required to develop guidelines, targeting clinicians and REB’s pertaining to consent, governance, and compliance requirements for clinical data transitioning to research use.