Use of a Registry That Includes Patient Reported Outcomes

Please provide any feedback regarding this scenario in the comment form below or by clicking here.

Max Researcher is a pain researcher with an NIH-approved study of post-surgical pain after knee replacement. Max would like to access and analyze data from a Joint Replacement registry containing functional status PROs that were created bya State-Funded contract (see PRO registry Creation Scenario). Max is conducting a study on the variability of outcomes after knee joint replacement.

The registry includes records of surgery details and PROs that were collected under a variety of agreements. Records included in the registry are subject to different terms governing research use:

1. Patient consented to data collection for quality improvement, but declined to permit release of data for research.
2. Patient consented to data collection for quality improvement, but was not asked about research use of data.
3. Patient consented to data collection for both quality improvement and research.
4. Data collection occurred during clinical operations and no formal consent was obtained. The activity of creating the registry was considered human subjects research by the IRB, but data are transferred under a waiver of authorization for research by the Privacy Board or Institutional Review Board for the Hospital and a contractual Agreement between the Health System and the registry.
5. Data collection was not considered Human Subjects Research by the IRB and data are transferred under Quality Improvement provisions and released under a contractual Agreement between the Health System and the registry.

The registry has its own accredited IRB, which all organizations have agreed will approve research activities that involve using the data. Max Researcher receives approval by the registry IRB and her own IRB for an NIH-funded research protocol that involves selecting all knee replacement patients and contacting them for an interview about post-surgical pain. The researcher pays a small fee to the registry to cover the costs of data management and registry overhead costs.

Questions:

- Given that the data in the registry is obtained under a mixture of informed consent, waivers, and business associate agreements, how should these conditions be tracked?
- Given that the registry contains PRO data, which in some cases patients have consented for research use (and in other cases not), what, if any, are the researcher's obligations for the use of data without explicit patient consent? How should the entity managing the registry deal with consent and data use?
- Does the fee affect real or perceived ethical concerns?
- Would concerns be different if the research obtained IRB approval for use of deidentified data, with some concerns for re-identification?
- Do concerns differ if the PROs include instruments intended to measure post-surgical depression?
- What additional protections must be in place given the availability of the limited data set?

Title	Response
Description	A registry contains health data and PROs approved for research purposes, and each record has been approved under different conditions.
Primary actor/participant	Researcher (end-user) using registry
Support actor/participant	Registry-affiliated entities who submit clinical data, patients who submit PRO data
Preconditions	• Registry has been created with all necessary approvals • Approval of research protocols by IRB • Payment to cover costs of data extraction has been obtained • The registry manages the data submitted by participating data sites, and manages that store relevant information for a given protocol/study.
Post conditions	• The researcher accesses registry data electronically by the researcher (clinical data, and PROs). • Researcher has access to data set and is able to analyze/combine them for a specific research study. • Researcher contacts patients and collects additional PRO data.
Alternatives	• Max is a member of the public interested in analyzing registry data. • Max's study does not involve contacting patients, but analysis of a limited data set with some risk of re-identification. • No fees are charged. • PROs contain measures of substance misuse/substance use disorders relevant to pain treatment that may have implications beyond screening for depression. • PROs include measures of depression as well as functional status. • Do other concerns apply if data submission to the registry is mandated by state law?

Considerations	• Tracking conditions for the registry data that is obtained under a mixture of informed consent, waivers, and business associate agreements • Researcher's obligation, if any, to obtain explicit patient consent for the data patients may or may not have consented for research use • Whether the PROs include instruments intended to measure post-surgical depression
Data Elements Considered	Electronic data from multiple sites and patient reported outcomes,
Purpose of the Data Collection	Improved clinical care and patient outcomes
Purpose of Data Use	Analysis under a specific research protocol
Terms of Transfer to the Data Holders	DUA between organizations, informed consent
Terms of Transfer to Researchers	IRB approval and terms of consent or other agreements

Unknown macro: 'iframe'