Project Charter

Project Charter (Draft Version)

This document expresses the goals and scope of the research data use scenarios that will be developed for the “Patient-Centered Outcomes Research (PCOR) Privacy and Security Research Scenario Initiative and Legal Analysis and Ethics Framework” project.

Project Context

This project will address how health information derived from a wide variety of data sources can be used for patient-centered outcomes research (PCOR) and comparative effectiveness research (CER), consistent with ethical principles and legal and regulatory requirements related to patient consent, privacy, and autonomy. A companion project led by the Centers for Disease Control and Prevention (CDC) will focus on similar questions in the public health realm. The NORC-led initiative will address public health more narrowly, in terms of the use of relevant public health data sets and issues related to privacy and security in PCOR. The projects’ shared objective is to create a practical, technology-neutral legal and ethical framework that makes sense to researchers, patients, and providers and that can guide health IT developers and policy makers to responsibly use and protect data for PCOR and CER.

The first phase of our project will focus on developing research data use scenarios through collaboration with PCOR researchers, patients, providers, health IT technologists, privacy experts, and legal experts. The research data use scenarios will be distilled into use cases that outline the legal, policy, and ethical requirements. The use cases will be carefully constructed to include the actors, pre-conditions, post-conditions, goals, workflow, tension points, etc. related to each issue. The second phase will focus on developing the aforementioned framework that addresses the legal and regulatory requirements and ethical principles governing the use of health information for PCOR and CER. The two phases will utilize an online project collaboration space, which will facilitate the sharing of project documents so that the work of each phase will inform the other.

Finally, both the research data use scenarios and the legal and ethical framework developed during this project will be used by a related ONC project tasked with identifying or developing technical standards for capturing patient choice electronically, including basic choice for treatment, basic choice for research, and granular choice.

Framing of PCOR and CER

“Research” means any “systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”[1]

“PCOR” is research that incorporates:

1. Advanced approaches to assessing provider and patient preferences, health-related quality of life (HRQoL), clinical efficacy, potential side effects of treatment and drug therapies, and the impact of patient genetic predisposition and;
2. The capacity to capture, manage, and analyze data from providers and patients.

PCOR’s goal is to produce findings that give patients and providers an individually tailored view of their treatment options and the possible benefits and harms associated with a particular course of action, allowing the patient and provider(s) to make informed decisions about the patient’s health and healthcare.

“CER” is defined as "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels."[2]

Goals

The main goals for this project are to:

1. Develop research data use scenarios that describe the challenges and tension points that researchers encounter when capturing, managing, and using data for research.
2. Ensure that the research data use scenarios:
    a. Address key issues that researchers face that are representative of practical industry-wide needs,
    b. Acknowledge the patients’ interests around consent and privacy as central, and
    c. Are valuable for solving real-world PCOR/CER challenges;
    d. Describe how users and systems interact to identify data-sharing and system interactions and requirements across the research community;
    e. Leverage existing and ongoing federal and private sector work by incorporating and referencing existing and ongoing work in the research data use scenarios to avoid duplication, including relevant work being conducting by other PCOR projects across ONC; and
    f. Analyze various operational elements, technical policy requirements, tasks, activities, and information-sharing necessary to support the PCOR/CER community. These will include, issues of access, consent, privacy, security, and other relevant issues.

Target Outcomes

We will convene a group of PCOR/CER stakeholders via work group meetings and online collaboration, and facilitate an interactive process to develop 15-20 priority research data use scenarios. These scenarios will describe user actions, system interactions, and information-sharing requirements for PCOR and CER. In developing the research data use scenarios, the NORC team will draw upon federal and private sector work related to privacy and security for PCOR/CER, and engage with a broad range of stakeholders including: patients, patient advocates, providers, payers, researchers, health IT vendors, standards organizations, public health organizations, and federal agencies.

A range of scenarios will be constructed and then examined to determine the different ways PCOR and CER researchers might interact with electronic health records (EHRs) and other systems that manage individually identifiable health information. The scenarios will inform the legal, regulatory, and ethical framework developed during Phase 2 (PCOR Legal Analysis and Ethics Framework).

In-Scope

Our task is to identify the policy, legal, and ethical components and requirements to support data use in PCOR and CER while protecting patient privacy.

We will consider issues related to data characteristics (identifiability, type, source), data handling (storage, transmission, collection), data uses (purpose, scope of consent), the users and facilities interacting with the data (collector, data user, location of collection and use), as well as others raised by the work group.

We will focus on:

- Identifying research data use scenarios that are person-centric and encompass PCOR and CER;
- Identifying necessary policies and requirements to enable data use in research;
- Defining the gaps and needs in policies and ethical and legal requirements; and
- Identifying instances where technical components intersect with policy requirements, referencing relevant technical specifications as needed

In addition to clinical and administrative data, other data types of interest include: patient-generated health data; genomic data; bio-specimens; behavioral health; alcohol and substance abuse; social media; registries; survey data; social determinants of health; and data from special populations of interest, including under-represented and culturally diverse populations.

Out-of-Scope

- This initiative will not include data use scenarios focused on provider or payer operations or on educational records.
- This project will not attempt to address data “ownership” issues, focusing instead on enabling data use for advanced research.
- This project will provide specific guidance related to IRBs.
- Research and development activities undertaken at private companies will not be included.
- We will not identify or develop solutions (technical or otherwise); this will be the work of other planned and future initiatives.

Examples of Possible Topics for the Scenarios

The stakeholder group will work together to brainstorm topics for the research data use scenarios and then to fully describe and develop those scenarios and their specifications. Some possible areas of interest include, but are not limited to:

- Data collection and sharing for research purposes;
- Merging large databases for research purposes;
- Research related to precision medicine;
- Research/information-sharing within and across multiple entities;
- Laboratory data for research purposes;
- Patient-generated data used for research purposes;
- Familial/community implications of research data collection and use.

Timeline

The research data use scenarios will be developed through collaboration with the multi-stakeholder group, beginning with the kickoff meeting on December 1, 2015. During an intensive process with the group, we will develop draft scenarios and submit them to ONC in February 2016. After obtaining ONC’s feedback on these draft scenarios, we will submit revised scenarios to ONC in May 2016. After a period of discussion and revisions, in August 2016, we will circulate the revised scenarios across the larger research community for comment. The scenarios will be finalized and submitted to ONC in October 2016.

---

[1] 45 CFR § 164.501
[2] IOM Initial National Priorities for Comparative Effectiveness Research, Chapter 2 (2009) at http://www.nap.edu/read/12648/chapter/4#30