Databases and Registries
Quality Improvement/Assurance or Research?

OHRP Community Research Forum
Best Practices for IRB Chairs and IRB Members
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Databases and Registries

- Number and Scope expanding rapidly
- Participating in 30+ external initiatives
- Types
- The "biological specimen" bank for data

- The question is:

  Are these initiatives quality improvement and/or assurance or are they research?

Definitions

- Quality Assurance
  - A formal approach to determine if following policy/protocols
  - Generally retrospective
- Quality Improvement
  - A formal approach to the analysis of performance and systematic efforts to improve it
  - Potentially both prospective and retrospective
- Research
  - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

45 CFR Part 46.102

Research or Quality?

- Many initiatives indicate they are quality and not research
- Cite OHRP frequently asked questions "Do quality improvement activities fall under the HHS regulations for the protection of human subjects in research (45 CFR part 46)…"
  - No, such quality improvement activities do not satisfy the definition of "research" under 45 CFR 46.102(d), which is "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge…" Therefore the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.
- Often fail to consider the whole question "…if their purposes are limited to: (a) delivering healthcare, and (b) measuring and reporting provider performance data for clinical, practical, or administrative uses?

The IRB

- To protect the rights, safety and welfare of all individuals participating in research
- To ensure research is conducted according to applicable regulations and standards
- To minimize the administrative burden of conducting research

What role does the IRB have in the oversight databases/registries?

Back to the Basics

1. Is the database/registry research?
2. Does the database/registry involve human subjects?
3. Does the database/registry qualify for an exemption?
4. Is the institution engaged in research?

Back to the Basics 2

1. Is the database/registry research?
   a **systematic investigation**, including research development, testing and evaluation, designed to **develop or contribute to generalizable knowledge**

2. Does the database/registry involve human subjects?
   a living individual about whom an investigator (whether professional or student) conducting research obtains
   (1) Data through intervention or interaction with the individual, or
   (2) **Identifiable private information**.

45 CFR Part 46.102

Identifiable Private Information

1. Names
2. Address
3. All elements of dates (except year) including admission date, discharge date
4. Telephone number
5. Fax number
6. E-mail address
7. Social security number
8. Medical record number
9. Health plan beneficiary number
10. Account number
11. Certificate/license number
12. Vehicle serial number
13. Universal Resource Locators (URLs)
14. Device Identifiers and serial numbers
15. Internet Protocol (IP) address numbers
16. Biometric indicators such as fingerprints or voiceprints
17. Full-face photographic images and any comparable images
18. Any other uniquely identifying number, characteristic, or code.

45 CFR Part 164.514(b)(2)(ii)

Back to Basics 3

3. Is the database/registry exempt from IRB oversight?

Research involving the collection or study of **existing data**, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects **cannot be identified**, directly or through identifiers linked to the subjects.

4. Is the institution engaged in research?

Institutions whose employees or agents **obtain** for research purposes identifiable private information or identifiable biological specimens **from any source** for the research.

45 CFR 46.101(b)(4)

Issues

- Overarching databases/registries
  - Collection of all patients undergoing a certain procedure or with a certain disease state
  - May or may not have a specific question in mind
  - Similarities to a biological specimen bank
  - How to handle "withdrawals"
- Definition of "Readily Ascertain"
  - Do all elements of identifiable private information allow patient identification
- Who is the Investigator?
  - obtaining versus releasing information
- Who is considered Key Personnel?
- Alternative mechanism for handling databases/registries

Current Thoughts

- Most databases and registries are considered research
- Only those that contain PHI are considered research involving human subjects
- Generally not exempt
- Local IRB review and oversight required