Records-Based Research

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Introduction

Researchers can make important advances in the fields of education, medicine, psychology, and public policy without any in-person interaction with human subjects. Rather, hypotheses can be posed and answered by analyzing documented information in various types of paper or electronic records (such as, medical, motor vehicle, criminal justice, or school records).

Each person conducting scientific research based on records should:

- Understand the specific risks to human subjects associated with such research.
- Ensure that the research plan specifies procedures that minimize those risks.
- Obtain all required approvals (organizational, state, federal, and international, if applicable) before conducting the research.

Before collecting information from records for research purposes, a researcher should consult with:

- The Institutional Review Board/Independent Ethics Committee (IRB/IEC) at his/her organization to determine the type of review required (if any); and
- The applicable administrator at the organization where the actual records are owned or maintained to ensure ability to access them for research purposes.

In addition, the researcher needs to determine if there are other regulations affecting the record-review. Examples include the Health Insurance Portability and Accountability Act's (HIPAA) Privacy Rule for medical records research, or the Family Educational Rights and Privacy Act (FERPA) for student education records.

Learning Objectives

By the end of this module, you should be able to:

- Discuss the risks associated with conducting records-based research.
- Identify the types of review that apply to records-based research.

Risks of Records-Based Research: Privacy and Confidentiality

Risks associated with records-based research stem from possible invasion of privacy and breaches of confidentiality. For example, the possibility that disclosure of the information could reasonably place the subject at risk of criminal or civil liability and/or be damaging to the subject's financial standing, employability, or reputation.

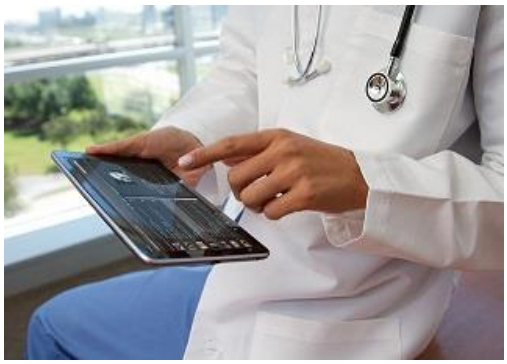
Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) or information about oneself with others. In the context of research, privacy risk pertains primarily to the methods used to obtain information about subjects. Whereas privacy risks are obviously very low in studies when a subject actually consents to providing personal information, they are much higher, in records-based research, when information is obtained for research purposes without the consent of subjects.

Confidentiality pertains to the actual treatment of the personal information once it is obtained. In other words, now that the researcher has obtained private information, how will it be used, stored, and reported in a way that is consistent with the manner under which it was originally obtained from the individual? Information from public records, and information obtained under a relationship of trust, as in the doctor-patient relationship, will require different considerations for protecting confidentiality.

Records-based research must balance the possible benefits of answering important research questions with the possible risks of using information about individuals, especially if information is used without their consent.

Imagine, for instance, the consequences to an individual if information provided to his/her medical doctor about their drug addiction was revealed to law enforcement officials, or mental illness was revealed to an employer. The IRB/IEC carefully reviews the procedures that are described by the researcher to protect the confidentiality of the information being accessed, including identification of all individuals or groups who may also be able to access that information. For example, a university's audit office, or a research sponsor may require access to the information to ensure that the research activity is being conducted appropriately.

Minimizing Risks



There is an ethical and regulatory responsibility to minimize research risks to human subjects. The risks of invasion of privacy can be minimized by obtaining informed consent from subjects (even, perhaps, before their records are accessed to determine their eligibility). However, for a variety of reasons, obtaining informed consent may be impracticable, may compromise the goal of the research, or may actually put the subject at greater risk. In these circumstances, the IRB/IEC may waive the necessity for informed consent if specific regulatory criteria are met:

- The research involves no more than minimal risk;
- The risks and welfare of the subjects will not be adversely affected by the waiver;
- The research could not practicably be carried out without the waiver of consent; and
- When appropriate, the subjects will be provided with pertinent information after participation.

The risks of breach of confidentiality associated with records-based research are necessarily tied to the confidentiality and sensitivity of the requested information. If the information is recorded without identifiers, the sensitivity of the information is less of a concern. If the information is both identifiable and sensitive, methods to protect confidentiality must be carefully considered by the researcher, and reviewed by the IRB/IEC. Therefore, in considering the research hypothesis, the researcher must assess how important it is to be able to associate the individual with his/her information.

Whenever possible, and to the greatest extent possible, de-identified or anonymous information should be recorded. Assuming the research cannot be conducted anonymously, the following questions speak to protection of the collected information. Based on a researcher's answers, an IRB/IEC will carefully assess whether possible risks from breaches of confidentiality have been minimized:

- What kind of identifiable information (if any) will be collected?
- Who will have access to the identifiable information?
- Where will the identifiable information be kept?
- What kinds of codes or encryption will be used to separate research data from subject identifiers?
- How will limitations on access be ensured?
- How will research staff be trained about privacy and confidentiality?
- How long will identifiable information or linkages to personal identifiers be kept?
- For data being transmitted physically and/or electronically, what encryption methods will be used?

- What procedures will be used for disposal/destruction of identifiers and research documents, once no longer required?

Certificates of Confidentiality

For studies in which identifiable, sensitive information is being accessed (such as, HIV status, history of alcoholism, or mental illness), the researcher may obtain protection from subpoena of his/her records by receiving a study specific Certificate of Confidentiality from the National Institutes of Health (NIH) or other HHS agency. For more information, visit the NIH's "Certificates of Confidentiality (CoC) Kiosk".

Under a new policy issued 7 September 2017 (effective 1 October 2017), NIH-funded investigators do not need to apply for a CoC, nor will they receive a document certificate. The NIH issues CoCs automatically for "NIH funded grants, cooperative agreements, contracts and intramural research projects research funded wholly or in part by the NIH that collects or uses identifiable, sensitive information" (NIH 2017). CoCs contain conditions for disclosure of the identifiable, sensitive information that the investigator must comply with , including more restrictive requirements for disclosure in the new policy.

The CoC policy remains the same for non-federally funded research, in that investigators must apply for a CoC from the NIH or other HHS agency for specific research studies.

What Type of Review is Required for Records-Based Research?

Record-based research can fall into one of four review types. To identify the appropriate type of review, consider the following four questions:

- Do the activities meet the federal definition of "human subjects research?"
- Is the research eligible for exemption from the federal regulations?
- Is the research eligible for expedited review under the federal regulations?
- Does the records-based research need review by the full/convened IRB/IEC?

Some organizations have criteria more stringent than the federal regulations and guidance, so the information provided in this specific section may not describe policies and procedures at the researcher's organization. Check with the applicable IRB/IEC office to find out how your organization makes such determinations.

Do the Activities Meet the Federal Definition of "Human Subjects Research?"

Record-based research activities may not meet the federal definition of human subjects research. HHS regulations at 45 CFR 46 (Protection of Human Subjects 2009) define a human subject as "a living individual about whom an investigator (whether professional or student) conducting research obtains[:]

- Data through intervention or interaction with the individual, or
- Identifiable private information."

To apply this definition, the individual designated by the organization to make this decision, will consider:

- Do the records involve living individuals?
- Were the records collected specifically for this research project through intervention or interaction with the individual?
- Can the researcher readily ascertain the identity of any of the individuals either directly or indirectly through coding systems?

The researcher should check with the IRB/IEC to determine who has the authority to make this decision whether the research constitutes human subjects research, or whether the organization's policy is more stringent.

If the research involves coded private information, please refer to OHRP's *Guidance on Research Using Coded Private Information or Specimens*.

Is the Research Eligible for Exemption from the Federal Regulations?

Record-based research may be exempt if:

- The information is existing (on the shelf) at the time the exemption is requested; and
- The information sources are publicly available (any person can obtain the data), or the information is recorded by the researcher in such a manner that subjects cannot be identified (directly or through identifiers linked to the subjects). Although the researcher may actually see identifiers while reviewing the data set, he/she cannot record any of them in any research record, or data collection instrument.

OHRP recommends that researchers do not determine if their research qualifies as exempt. Rather, the organization should designate an applicable institutional official (or the IRB/IEC) to conduct this review. Organizations may have internal rules and policies in addition to the federal regulations that will determine whether to grant the exemption.

Is the Research Eligible for Expedited Review Under the Federal Regulations?

Record-based research may qualify for expedited review if the research activity:

- Poses no more than minimal risk of harm or discomfort to the subjects; and
- Is described in one of the **expedited review categories** (OHRP 1998): Records-based research that is eligible for expedited review generally falls under Category 5, "Research involving materials (data, documents, records, or specimens) that

have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)."

Expedited Category 5 described above differs from the exemption category associated with existing records. The exemption category applies only to retrospective research, while the expedited category applies to prospective as well as retrospective research.

Does the Record-Based Research Need Review by the Full/Convened IRB/IEC?

If the human subjects research does not qualify for exemption or expedited review, then it must undergo full review by the IRB/IEC at a convened meeting.

When Health Information is Involved: The Federal Privacy Law

When records-based research requires access to individually identifiable ("protected") health information, additional requirements of the federal Health Insurance Portability and Accountability Act (HIPAA) must be met. This includes the need for written authorization from the patient, above and beyond informed consent requirements under the Common Rule. Promulgated through the Office of Civil Rights (OCR), requirements under HIPAA vary depending on the type and number of identifiers that are being associated with the accessed health information. If most, but not all, mandated identifiers are removed (a "limited data set"), written patient authorization may not be required, provided there is a data use agreement between the researcher and the organization holding the medical records. If any more identifiers are added to the set, either written patient authorization is required, or a HIPAA Privacy Board can grant a waiver of authorization based on similar criteria to those required for waiver of consent under 45 CFR 46. Health information that is completely “de-identified” as defined under HIPAA, is not subject to the privacy law.

Records-Based Research

Dr. McGill has designed a research plan to compare the rates of re-admission of patients with severe community-acquired pneumonia treated with two different antibiotic regimens. She plans to look at data from the past 12-months. The electronic medical record (EMR) system that the hospital uses can be queried by the billing department to generate a report that includes a specific data set. In order to obtain a sufficient sample and minimize bias, Dr. McGill will collect the same data set from three other hospitals using the same EMR system, but located in different regions of the country. Colleagues at the other hospitals have agreed to collaborate on this research. Each of the data sets will include protected health information (PHI), but direct identifiers (such as, name, medical record number, and patient account number) will be stripped from the data sets and replaced with a code before they are sent to Dr. McGill. The researcher at each hospital will retain the key to the code for the subjects from each of their organizations so that they verify data in the medical record if necessary. Each researcher will maintain the key to the code in a secure location separate from the data set. The data sets themselves will be retained and transmitted in an encrypted format at each organization. Dr. McGill has requested a waiver of the requirement to obtain informed consent and HIPAA authorization.

- What risks of harm could the subjects be exposed to?

  Subjects whose medical records are reviewed are exposed to potential harms from invasions of privacy and breaches of confidentiality. Privacy involves having control over the sharing of oneself or information about oneself with others. When the requirements for informed consent and authorization are waived, individuals lose the autonomy to determine and control access to their information. Confidentiality involves the safeguarding of private information once it is obtained and recorded. Even with strong safeguards in place, breaches of confidentiality are possible and can result in individuals being exposed to psychological, reputational, financial, and other harms.

- What is the minimum level of review for which Dr. McGill's research is eligible?

  The IRB/IEC may use an expedited review procedure to review this research. Because each researcher may access identifiable information for research purposes and holds the key that allows re-identification of local subjects, this research involves human subjects and is not eligible for exemption. As the type of data being collected and the proposed methods to secure the coded data sets minimize the likelihood and potential effect of a breach, the IRB/IEC might assess the research's risk as no greater than minimal. Also, because the

research involves records that were gathered for clinical purposes, not specifically for this research, the research activities fall under one of the expedited review categories. The request for the waiver of the requirement to obtain informed consent and HIPAA authorization also may be reviewed by an expedited review procedure.

Summary

Although there is no direct interaction with human subjects in records-based research, there may be risks to those individuals who originally provided the information used in such activities. Those risks must be minimized, informed consent must be considered, and review and approval from the organization and IRB/IEC must be obtained, per local, state, and/or federal regulations. Research involving identifiable health information requires compliance with additional federal requirements.

References

- National Institutes of Health (NIH). 2017. "Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality." Accessed 14 September.
- Protection of Human Subjects, 45 CFR § 46 (2009).
- U.S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP). 1998. "OHRP Expedited Review Categories (1998)." Accessed March 15, 2016.

Additional Resources

- National Institutes of Health (NIH). 2015. "Certificates of Confidentiality (CoC) Kiosk." Last updated October 28.
- U.S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP). 2008. "Guidance on Research Using Coded Private Information or Specimens." Accessed March 15, 2016.

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