Research involving Records

1 Introduction

Scientific investigators have made many contributions to knowledge, medical practice, and public policy, by collecting information from various kinds of records. These sources include medical records, motor vehicle records, criminal justice records, and school records.

Most of these records at one time existed only on paper. However, many now also exist in the form of computerized databases, which have greatly facilitated research but have also raised additional privacy concerns. Each person conducting scientific research based on records should:

- **Understand concerns about inappropriate access and unauthorized disclosure.**
- **Have procedures in place to protect the confidentiality of the records while in use and of the information collected.**
- **Obtain all required approvals (institutional, state, federal, and international, if applicable) prior to conducting the research.**

Before collecting information from records for purposes of research, an investigator should consult with the Institutional Review Board (IRB) at his/her own institution. He/she should also contact the appropriate administrator at the institution where the records are owned or maintained.

2 Risks of Records-Based Research

These risks concern privacy and confidentiality. Risks stem from the possibility that disclosure of the information could reasonably:

- Place the subject at risk of criminal or civil liability.
- Be damaging to the subject's financial standing, employability, or reputation.

Some records studies involve data collection only from existing records, while other research may combine data collected from records along with data obtained directly from subjects. The risk level may be increased when a study has multiple avenues of data collection.

The IRB will carefully review the procedures that are in place to protect the confidentiality of the information being collected. Investigators are generally

asked to describe who will have access to identifiable private information and how inadvertent disclosure will be prevented.

3 Privacy/Confidentiality

3.1 Privacy

Privacy generally means the state of being free from intrusion into one's personal life. In the context of recorded information, it refers to an expectation or, in some cases, a legal right of a person to control access to personal information about himself/herself.

3.2 Confidentiality

Confidentiality is an ethical principle, generally based on trust, that personal information will be kept secret, unless the person about whom the information has been collected permits disclosure or unless disclosure is warranted for exceptional circumstances, such as to prevent a harm.

3.3 Balance

Research using records must balance access to information in the service of important societal goals with the need to protect sensitive information about the health or behavioral characteristics of individuals. Information about a particular person, if disclosed inappropriately or in the wrong context as a result of research, could be harmful to that individual. Consider the following possible scenarios:

- A person could be ostracized if community members learned that he or she had - been accused of partner abuse.
- A parent could punish a minor child if he/she discovered that the teenager was sexually active.
- A person's chance for a promotion at work could be damaged by the discovery that he/she has a psychiatric diagnosis, heart disease, cancer, or some other medical condition.

4 Minimizing Risks

Three important components of minimizing risks in records-based research are:

- **Respect for Persons,** which concerns the rights of individuals to decide how confidential information will be used and disclosed,

- **Integrity**, which pertains to the conduct and ethics of study investigators, research staff, and institutional staff,

- **Security**, which focuses on the protection of data and people from inappropriate access or actions.

4.1 Respect for Persons

Individual privacy can be most completely protected by obtaining the consent of the research subjects and by using data collection and security procedures that are very stringent. When consent is obtained, the subject whose data will be used has an opportunity to learn how the information about him/her will be used and how it will be protected. Through the consent process, the investigator can describe directly to the research subject the extent to which confidentiality---safeguarding information based on trust---will be maintained. The research subject can then decide if he/she will permit the use of information about himself/herself.

4.2 Research Integrity

In some cases, it may not be possible to contact and obtain consent from all the individuals whose information is needed for a particular research effort. Some records-based research may need to use thousands of medical records, for instance, when rare adverse events of a particular medication are the subject of a study. If an IRB agrees that obtaining consent of the research subjects is not feasible and determines that all federally required conditions have been met, the IRB will approve research only if when it includes very clear data security procedures. Because virtually all kinds of information in records used in research could be harmful if inadvertently or improperly disclosed, it is important to ensure that all information collected for research purposes has equally strong protections. When an IRB has determined that it is not practicable to obtain consent and the risks of the research are reasonable in relation to the potential benefits of the research, the investigator describes confidentiality protections to the IRB, rather than directly to the subject. In a sense, the trust relationship is then between the investigator and the IRB, who represents the research subject. Therefore, it is important for IRB applications to provide information about the training and experience of investigators and research staff to document knowledge of procedures that will protect the research subject.

4.3 Security

Federal regulations *require* that IRBs approve only research projects that are designed to minimize risks. *Therefore*, following the institution's procedures, the IRB will review data security procedures so as to assess the following:

- What kind of identifying information will be collected?
- Who will have access to the identifying information and the research data?
- 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 persons be trained about privacy and confidentiality?
- Will research staff be required to sign an oath of 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 documents?

Although IRBs assess these same protections as part of their review of all research studies, records-based studies often present a particular challenge because of the possibilities of utilizing and linking various data sources.

5 Categories of IRB Review: Full IRB Review or Expedited IRB Review?

Some IRBs may review records-based research using an *expedited* process and some may require *full* board review. A full IRB review is done at a convened meeting of the IRB membership, while a Chair or one or more experienced IRB members designated by the Chair may conduct an expedited review.

Many IRBs consider most record review studies to be "minimal risk", and therefore, they may be reviewed using an expedited process. However, each institution may consider the following in determining which studies present minimal risks to subjects:

- What is the nature and sensitivity of the data?
- What data, if disclosed outside the research setting, might cause harms?
- What study procedures, such as encryption methods, will be in place?
- How experienced are the investigators and their staff?

Also, each institution may have a different procedure for deciding whether full or expedited review is required and perhaps a different application form for minimal risk studies. Be sure to check with the IRB where you are requesting review to find out what type of review is required for your records study.
Investigators should remember that, in this context, "expedited" does not necessarily mean "quick." Research applications may need to be mailed to one or more IRB members, after which the reviewers may recommend that the IRB

Chair approve the study or that it be reviewed at a full IRB meeting. Research may not be disapproved using an expedited process, so, in some cases, review may be delayed because a project is forwarded to a full IRB meeting.

6 Records-based research that may be eligible for an application for exemption

Generally, an IRB must review and approve all research that includes review or collection of existing data, documents, or records relating to identifiable human subjects. However, there are some instances in which such research is exempt from the federal regulations (45 CFR 46). Records research can be certified by an institution or IRB office as exempt when:

- The sources of information are publicly available or
- The information collected is recorded by the investigator in such a way that the subjects cannot be identified, directly or indirectly, through identifiers linked to the subjects.

Research conducted solely with publicly available data are exempt, unless the institution has a policy to the contrary. Publicly available data must be truly publicly available to anyone, regardless of an individual's status as a researcher. For example, publicly available data may be available for purchase.

In order for research using records to meet criteria for exemption according to 45 CFR 46 101b, the records must already be "existing," i.e., the information in the records must have been collected already. *If the investigator will be able to identify the subjects directly from his/her research records, the research cannot be considered exempt from review.* An investigator may maintain a mechanism for identifying subjects (e.g., keeping the subjects' names or other identifying information or keeping a "crosswalk" between a study number and a person's name or other identifier). Most institutions would not consider research with this kind of indirect link to identifiers to be exempt. However, in some cases, when the investigator does not have access to identifying information on the subjects, research may be declared exempt by an institution or IRB if a signed agreement is in place between the investigator and the original record holder stating that identifiers will never be given to the investigator.

Even if a study meets the federal requirements for exemption, it might not be considered exempt according to institutional policy or state law. Describing your study procedures in writing in accordance with institutional requirements is the best way to find out whether IRB review is required at your institution.
The most important point to remember about "exempt research" is that a determination of exemption must be made at the institutional level in accordance with institutional policies.

Most institutions have a procedure by which an investigator can request a Certificate of Exemption or receive a written certification that the institution has determined that the research is not subject to 45 CFR 46. OHRP has provided guidance on this issue.

7 Consent Requirements

Consent/Authorization or Waiver of Consent?
For all research, including records-based research, the investigator must obtain the consent of the subject unless the IRB has determined that it will approve a waiver of consent. According to DHHS regulations, informed consent from the subject must be obtained unless all of the following conditions are found and documented:

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

In addition, the HIPAA Privacy Rule requires a written authorization from subjects for use of their protected health information, unless an IRB approves a waiver of authorization based on similar criteria to those listed above (see the "HIPAA and Human Subjects Research" Module for more information about HIPAA requirements).

Most IRB applications require that an investigator who is requesting a waiver of consent provide a written justification for this. This justification should address both the requirements of 45 CFR 46 and of HIPAA, and any additional requirements of state law and institutional policies. In assessing the justification, the IRB will ask, among others, the following questions:

- Is a particular record-based study of "minimal risk" to the subjects?
- How many subjects are in the study and is it possible to locate them so that consent can be requested, obtained, and documented?

Note that cost alone ("it would cost too much") is not considered to be an adequate justification for a consent waiver.

8 Conclusion

Each institution where records reside generally has policies and procedures governing their use by internal staff and by external investigators. Similarly, each state may have laws pertaining to particular kinds of records. For instance, in Washington State, there is a statute outlining under what conditions information contained in medical records may be released and to whom it may be released. Therefore, each investigator conducting records-based research should consult with the Institutional Review Board (IRB) in the state where they are working for information on requirements that apply to the research they are proposing to conduct.

It is recommended that investigators take advantage of IRB review (or other institutional resources or consultations) when designing records-based research and the procedures that can be used to guard privacy and confidentiality. In order to maintain public trust in research, it is important that it is done in a way that provides maximum protections from risks to individuals, while furthering contributions to society's knowledge.