

The National Human Research Protections Advisory Committee (NHRPAC) approved the following recommendations on Confidentiality and Research Data Protections at the July 30-31, 2002 Committee meeting.

## **Recommendations on Confidentiality and Research Data Protections**

### **National Human Research Protections Advisory Committee**

**These recommendations are intended to advise the Secretary and Assistant Secretary for Health, Department of Health and Human Services, as well as the Director of the Office of Human Research Protections. They may be used in the preparation of guidance for local Institutional Review Boards or in issuing advice to research investigators.**

Researchers in the biomedical as well as social and behavioral sciences are expected to be proactive in designing and performing research to ensure that the dignity, welfare, and privacy of individual research subjects are protected and that information about an individual remains confidential. This expectation is expressed in the ethical codes of conduct of professional societies. Protecting the confidentiality of information collected about individuals is also vital to fulfilling the ethical responsibilities described in the Belmont Report.

Research in the biomedical and social sciences encompasses a broad array of topical areas, designs, and degree of risk. Many studies pose minimal risk to research subjects. Some studies, however, are inaccurately perceived as conveying minimal risk. In such studies, disclosure of identifiable data may present a significant risk to the subject as a result of the sensitive nature of the topic, the variety of social interactions, or possible financial or legal implications of the activity being studied. In such research, especially in the social and behavioral sciences, protecting the confidentiality of data collected from or about private individuals is often the key element in minimizing risk.

In addition to protecting research subjects from harm that might result from their participation in research, applying appropriate confidentiality protections provides other important benefits. Confidentiality protections minimize subjects' concerns over the use (or misuse) of the data. Subjects consequently provide more accurate information to investigators, thereby improving the data used in the analysis and thus the overall quality of the research. Confidentiality protections allow researchers to continue to conduct difficult research on important societal problems (e.g., drug abuse, the spread of HIV, genetic predispositions, high risk sexual behaviors, violence). Such research provides a scientifically-informed basis for making important public policy decisions and fosters advances in medicine and in all fields of science. The benefits of these results accrue not only to the research subjects, but to society at large.

Confidentiality issues need to be recognized and considered at every stage of the research process. These stages include the initial study design; identification, recruitment, and consent processes for the study population; security, analysis, and final disposition of data; and publication or dissemination of data and results.

Intentional or inadvertent breaches of confidentiality by investigators or their staff may occur. In addition, there may be attempts (usually in a legal context) to force or compel disclosure of confidential information for non-research purposes. The likelihood of such an attempt cannot be anticipated by virtue of the subject matter or setting of the research. [An informative overview of this issue can be found in Joe S. Cecil and Gerald T. Wetherington, Special Editors, *Court-Ordered Disclosure of Academic Research: A Clash of Values of Science and Law*. 59 LAW AND CONTEMPORARY PROBLEMS. Number 3, Summer 1996.] The purpose of this paper is not to address all dimensions of this issue, but to focus on those aspects that are especially important in protecting against breaches of confidentiality.

### **Reducing Risk Through Confidentiality Protections**

Confidentiality issues do not inhere in all human subjects research. For example, observation of behavior in public places where there is no interaction between the observer and the observed and where data are recorded in anonymous form involves no issue of confidentiality for subjects, investigators or IRBs. In some studies, the consent agreement establishes that research subjects neither seek nor want confidentiality (e.g., a political science study of legislative changes where directors of interest groups agree to participate knowing that what they report will be presented as part of the analysis of factors leading to change). In circumstances where a promise of confidentiality is not a part of an informed consent agreement, the protocol makes clear to IRBs the nature of the consent agreement and why biographical anonymity and confidentiality are not sought.

Issues of data confidentiality typically come into play when biomedical, social or behavioral science research involves data collection on identifiable individuals. Confidentiality protections should be developed consistent with the study design and the potential risk of harm from breaches of confidentiality. As the risk of harm incurred by disclosure increases, so should the level of protection from such harm. In some cases, the collected data may not require as high a level of security as in other cases (e.g., laboratory studies on the level of boredom associated with repetitive tasks does not involve the same risk of data disclosure as surveys of personal sexual orientation and experience; clinical laboratory data generally do not involve the same risk of disclosure as data from genetic testing or screening). In all cases where a promise of confidentiality is included in the consent agreement, it must be granted and secured—regardless of the level of risk.

Much of the risk in social and behavioral science research is related to inadvertent or unintended disclosure. An adequate data protection plan can and should reduce the

risk of such occurrences. The OHRP has clarified that the Common Rule allows institutions and IRBs the flexibility to review and approve appropriately designed confidentiality protections.

Protocols should be designed to minimize the need to collect identifiable data by determining whether there is a legitimate reason to collect or maintain identifiers. Data can often be collected anonymously, or the identifiers can be removed and destroyed after various data have been merged. When it is necessary to collect and maintain identifiable data, a data protection plan should describe the appropriate level of confidentiality protections based on the potential magnitude of the risk of harm from disclosure. All members of the research team and staff should receive appropriate training about securing and maintaining confidentiality and safeguarding data. Data should be physically secure, and all identifiable, confidential data not intended for secure archiving should be destroyed.

### ***Recommendation***

(1) OHRP should issue guidance to IRBs and the research community indicating that the degree of confidentiality protection required in research protocols be commensurate with the degree of risk of harm associated with the type of data collected. This guidance should emphasize that a good data protection plan can reduce or ameliorate the degree of risk of harm. (Such guidance will help IRBs in their work and will emphasize to individual investigators and their research teams the relationship between risk of harm and data protection.)

### **Confidentiality Protections**

Efforts can and should be made to buffer or insulate research data from encroachment. When a determination is reached that the sensitive nature of the data and the potential risk of harm to individual subjects occasion legally supported confidentiality protections, the investigator (with the support of the institution) should pursue appropriate protections.

One such mechanism involves securing a certificate of confidentiality from the Department of Health and Human Services for applicable categories of research (biomedical, behavioral, clinical, mental health, drug or alcohol abuse).<sup>1</sup> Another involves investigator and institutional compliance with mandatory confidentiality protections such as those provided through statutes covering the DOJ and DOEd.<sup>2</sup> It is important to note that each of these confidentiality provisions has important limitations. It may apply only to certain categories of research or to research sponsored by a specific agency. It may protect the identity of the research subject, but not the data. Or,

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<sup>1</sup> As provided under the Public Health Service Act [42 U.S.C. § 241(d)]

<sup>2</sup>US Department of Justice [42 U.S.C.§3789g and implementing regulations 28 CFR 22] or US Department of Education, National Center for Education Statistics [20 U.S.C. 1221e-1]

it may provide protection against compelled disclosure of data, but not voluntary disclosure (see examples in Table 1). OHRP should lead efforts to strengthen the current system of confidentiality protections.

Given the limits of these statutory protections, both investigators (and their research teams and staff) and their institutions are morally obligated to resist attempts to breach confidentiality through compelled or forced disclosures (e.g., subpoenas). This not only fulfills ethical obligations to the research subject, but also serves to prevent important breaches of confidentiality. It is important to note that courts may subpoena either data or investigators who have had conversations with participants.

### ***Recommendations***

(2) OHRP should clarify current research confidentiality protections, specifically (a) what certifications are available to protect data and how each certification works; (b) which agencies are authorized to grant which certifications; (c) when certifications may be sought; (d) exactly what each certification protects (e.g., only the identifiers or all of the data); and (e) what confidentiality gaps exist in certification (e.g., for some research, certificates of confidentiality that prohibit voluntary disclosure are needed). OHRP should lead an effort to ensure the adequacy of certificates of confidentiality issued by federal agencies.

(3) OHRP should lead a federal review of existing legal authorities, including statutes and regulations, that provide research confidentiality protections (see illustrative summaries in Table 2). This review should identify what the various laws protect, how the protections are obtained, who administers them, and where potential gaps in the protections exist. Where outstanding issues or gaps in research confidentiality are identified, a proposal to address these gaps in research confidentiality should be developed through a consensus process involving the scientific, research participant, and legal communities.

(4) OHRP should consider establishing an electronic clearinghouse linking information on all federal and state research confidentiality protections.

### **Limits in Confidentiality Protections**

In some instances, statutes and regulations limit when confidentiality can be maintained (e.g., mandatory reporting of child abuse), and IRBs and investigators need to consider such limits when evaluating confidentiality protections. Conflicts between the promise of any confidentiality safeguard and reporting statutes must be understood and resolved before the research begins. In such situations, it is important that all consent processes and documents and research protocols be designed and administered to describe clearly the limits on confidentiality so that subjects fully comprehend these limits when considering their participation. All potential conflicts between protecting confidentiality and requirements to release information (such as institutional policies or professional ethical requirements) should be explicitly communicated.

### ***Recommendation***

(5) OHRP should develop guidance for accurately and effectively describing confidentiality protections and limitations during the consent process. Special care should be given to describing how information will be maintained, when and under what circumstances confidentiality will or will not be maintained, and any reasonably anticipated risk associated with the disclosure of the information.

### **Institutional Support**

The role of the research institution crosses the spectrum of research activities from the beginning stages of the study to final disposition of research data. Thus, the institution plays a critical role in ensuring the confidentiality safeguards stipulated by their investigators and their institutional IRBs. Specifically, investigators and IRBs are responsible for ensuring, implementing and evaluating the efficacy of data protection plans, and institutions are responsible for supporting those plans and their mechanisms for evaluation consistent with existing legal protections.

### ***Recommendation***

(6) Host research institutions should recognize and fulfill their obligations to actively support the investigator in protecting all confidential information from compelled disclosure or as otherwise agreed to in the data protection plan. To this end, OHRP should require this institutional responsibility as a term and condition of the assurance, and any future accrediting bodies should establish requirements in this area.

### **Sharing Non-public Use Data**

As part of the research enterprise, scientists are encouraged by federal agencies and scientific societies to make their research data available to other scientists. This is often done in the form of public use files (discussed by NHRPAC in separate recommendations).<sup>3</sup> The primary investigator is responsible for ensuring that shared data are protected. Occasionally identifiable research records are transferred to another investigator for additional analyses (in accordance with IRB approval of such restricted use). In such circumstances, secondary users must agree to protect the confidentiality of data even when it is shared or transferred. Specific consideration should be given to (1) communicating explicitly the data protection plan that needs to be in place by secondary users; (2) determining whether the original consent agreement limited the use of the data in future studies; and, (3) obtaining a written and binding agreement from the recipient that the data are bound by all of the conditions governing its original collection.

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<sup>3</sup> NHRPAC adopted recommendations on Public Use Data Files at the January 28-29, 2002 Committee meeting. These recommendations address both the review of protocols to create public use data files and the use of such files. See NHRPAC website at <http://ohrp.osophs.dhhs.gov/nhrpac/documents/data/tr.pdf>.

***Recommendation***

(7) OHRP should develop guidance for use by investigators and IRBs clarifying that when identifiable data are shared by investigators, the same conditions for protecting and using the data that were present when the data were initially collected obtain for secondary users of those data.

**Table 1. Examples of Limitations and Differences in Federal Research Confidentiality Protections**

I. Confidentiality Protections Limited to Specific Research Categories

- Protections provided via HHS certificates of confidentiality (sexual attitudes, preferences, or practices; use of alcohol, drugs or other addictive products; illegal conduct; information damaging to financial standing, employability, or reputation; medical records which could lead to stigmatization or discrimination; psychological well being or mental health; genetic information). 42 U.S.C. §241(d)
- Research on drug abuse or other controlled substances. 21 U.S.C. §872(c).

II. Confidentiality Protections that Apply to Research Conducted or Supported by a Specific Federal Agency

- U.S. DOJ/Office of Justice Programs all research sponsored under the Omnibus Crime Control Act. 42 U.S.C. §3789(g) and 28 CFR part 22.
- U.S. Department of Education, National Center for Education Statistics
- U.S. Census Bureau. 13 U.S.C. §9 and 214.
- National Center for Health Statistics. 42 U.S.C. §242m(d)
- Agency for Healthcare Research and Quality. 42 U.S.C. §299c-3(c)
- Federal Statistical Confidentiality Order

III. Confidentiality Protections that Protect Against Compelled Disclosure but not Voluntary Disclosure

- Protections provided via HHS certificates of confidentiality
- Note: Most other federal statutes or regulations provide for release of identifiable data for other than research or statistical purposes if consent is obtained from the individual at the time the data are collected.

IV. Confidentiality Protections that Provide Conditions for Transfer of Identifiable Data

- U.S. DOJ/Office of Justice Programs. 28 CFR part 22.
- U.S. Department of Education, National Center for Education Statistics

V. Confidentiality Protections that Apply to Identifiable Information about Individuals and Organizations

- U.S. DOJ/Office of Justice Programs. 28 CFR part 22
- Agency for Healthcare Research and Quality. 42 U.S.C. §299c-3(c)