Sleeping Better at Night: 
Investigators' Experiences with 
Certificates of Confidentiality

by Leslie E. Wolf and Jolanta Zandecki

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Researchers often collect particularly sensitive data, such as information about sexual behaviors and illegal substance use, which could place participants at risk if confidentiality were breached. For example, HIV-infected individuals may be prosecuted for exposing others to the virus and substance abusers could face prosecution for possessing illegal drugs or for criminal activities (such as prostitution) that they engage in to obtain drugs. Researchers have an obligation to protect participants' privacy and the confidentiality of their data, and Institutional Review Boards (IRBs) are responsible for ensuring that they take appropriate steps to do so.

One important means of protecting sensitive research data is to obtain a Certificate of Confidentiality from the National Institutes of Health (NIH) and other units of the U.S. Department of Health and Human Services (including the Centers for Disease Control and Prevention and the Food and Drug Administration). The Certificate of Confidentiality is designed to protect identifiable, sensitive research data against compelled disclosure in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. It is appropriate for researchers to obtain a Certificate of Confidentiality when the information and data collected could negatively impact a participant's social position, employability, insurability, or financial situation. Sensitive research data include information about an individual's genetic make-up; psychological well-being; sexual attitudes, preferences, or practices; and substance abuse or other illegal risk behaviors.

The literature on the Certificate of Confidentiality is limited, with most of it focusing primarily on educating researchers about the protection it provides and how to obtain one. Commentators have suggested that a Certificate of Confidentiality could protect researchers against compelled disclosure when they conduct studies on violence and victimization; research on nursing; genetics, and HIV; and research involving multiple sites. One commentator has questioned the value of obtaining a Certificate of Confidentiality, at least in the context of genetic research. He suggests that researchers do not widely use the Certificate of Confidentiality for genetic research because they do not value the protection it provides, subpoenas for research data are rare, and disclosure about the Certificate in the informed consent process might foster unwarranted
Table 1. UCSF Investigator Interview Questions

1. Please describe the research project(s) for which you have applied for Certificate(s) of Confidentiality in the following terms:
   a. the type of study (e.g., questionnaire, medical records, clinical trial)
   b. the general research topic (e.g., genetics, HIV, cancer)
   c. the type of sensitive material collected (e.g., alcohol or drug use, sexual behaviors)
   d. how and where participants were recruited (e.g., through flyers, in clinic) *

2. To which institute(s) did you apply for your Certificate(s) of Confidentiality?

3. Why did you decide to obtain your Certificate(s) of Confidentiality?
   a. Did the IRB recommend that you apply?
   b. Did the funding agency recommend that you apply?

4. How long did the application process take from beginning to end?

5. Did you encounter any problems during the application process? If so, what difficulties did you encounter?
   a. Do you have any suggestions for other investigators for avoiding these problems?

6. Based on your experience applying for a Certificate(s) of Confidentiality, do you have any suggestions for facilitating the application process?

7. Based on your experience with Certificate(s) of Confidentiality, how useful do you think they are?
   a. Has your research data ever been subpoenaed? If so, could you describe the circumstances in which your data was subpoenaed? What was the outcome? *
   b. Would you recommend that other investigators apply for a Certificate of Confidentiality? For what types of studies?

8. If you have applied to different institutes, what differences, if any, were there in their approaches to Certificates of Confidentiality?†

9. What information, if any, about Certificates of Confidentiality did the NIH institute(s) require or recommend that you include in your consent form?

10. What reactions, if any, have potential research participants had to these disclosures?
    a. Does having a Certificate affect/help recruitment? *

* Additional questions asked during the late Winter 2005 round of interviews.
† Although we asked informants about institutional differences, most did not have that experience.

Concern about the confidentiality of data and information collected from research participants.  

A recent survey of investigators who obtained a Certificate of Confidentiality from three institutes at the NIH found that most of the Certificates were obtained to protect genetic research, though this finding might be the result of the types of research that is funded by the institutions in the sample.  The study also found that the use of a Certificate of Confidentiality was associated with certain institutions and individuals, suggesting that knowledge about the availability of the Certificate is not widespread.

This finding is consistent with those of another study that assessed the documentation of the use of a Certificate of Confidentiality (among other things) in the genetics research literature.  That study found that although a significant minority of genetics researchers (one-fourth) had obtained a Certificate of Confidentiality, none of them mentioned this in their publication. Moreover, only one-third of genetics researchers were aware of the Certificate of Confidentiality and the protection it gives. The authors of the literature review suggested that researchers note in the publications when they have used a Certificate of Confidentiality as a way to educate others about their availability.

Because gaps remain in our knowledge about investigators' experiences with the Certificate of Confidentiality, we probed further to learn about the application process and researchers' opinions about the usefulness of obtaining this form of protection for sensitive research data.

Study Design

We used the NIH Computer Retrieval of Information on Scientific Projects (CRISP) database to identify investigators who used a Certificate of Confidentiality. We searched the CRISP database for University of California San Francisco (UCSF) investigators who had an NIH grant in 2002 and 2003 for research that potentially addressed "sensitive" issues. Research was defined by us as potentially sensitive if the title or abstract of the project suggested that it involved research on genetics, HIV, substance use, or illicit behaviors. Accordingly, for each NIH institute or center, we first selected the investigators whose projects seemed most likely to have a Certificate of Confidentiality based
on the study title and abstract. If multiple eligible investigators were listed for an institute, we ordered contacts to include investigators who conducted research on different topics (e.g., not all HIV-related) and who came from different departments or research units.

We e-mailed the selected UCSF investigators to invite them to participate in a telephone interview and included a copy of the ten interview questions with the invitation (Table 1). Investigators who did not wish to participate could respond by e-mail, and we did not contact them further. If the investigator did not respond to our e-mail, we followed up by telephone. If the first person selected for contact did not have a Certificate of Confidentiality, refused to participate in our study, or did not respond to our inquiry, we contacted the next person on the list until we obtained an interview or exhausted the list for that institute. We continued with our interviews until we reached saturation in our data.16 The interview guide (Table 1) was used to conduct semi-structured interviews that included open-ended questions and standard prompts when necessary to encourage participants to elaborate or clarify their answers.

Eligible investigators needed to have obtained a Certificate of Confidentiality for their research, but did not have to have a Certificate for the study we used to identify them. We did not identify eligible investigators for two NIH institutes and one NIH Center (National Institute on Deafness and Other Communication Disorders (NIDCD), National Institute on Aging (NIA), and National Center on Minority Health and Health Disparities (NCMHD)). Investigators who were no longer at UCSF or whose studies did not involve human participants (laboratory or animal studies) or were conducted outside the U.S. were excluded from the study. The UCSF Committee on Human Research approved this study. Informed consent was obtained verbally from all participating investigators.

Results
We contacted and requested the participation from a convenience sample of 60 UCSF investigators drawn from the CRISP database. From this sample, 21 investigators were excluded because they did not have direct experience with a Certificate of Confidentiality and two were excluded because they were no longer at UCSF, leaving 37 eligible to participate. Nineteen investigators who had used a Certificate gave consent to be interviewed. Thirteen investigators did not respond to our request after two follow-up contacts and five investigators declined to participate, for a response rate of 51% (19/37).

Research Covered.
Investigators obtained a Certificate of Confidentiality for a variety of research topics, but most commonly (11/19) for projects that collected data on alcohol and drug use (Table 2). The majority of studies involved surveys and interviews (14); investigators also conducted clinical trials (6), ethnographic studies (4), studies collecting biological specimens (6), and a review from government records (1). Several research projects involved more than one research methodology.

<table>
<thead>
<tr>
<th>Table 2. Research Activities Covered by a Certificate</th>
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<tbody>
<tr>
<td>Research topics*</td>
</tr>
<tr>
<td>Collecting genetic information</td>
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<tr>
<td>Collecting information on psychological well-being of subjects</td>
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<tr>
<td>Collecting information on subjects' sexual attitudes, preferences or practices</td>
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<tr>
<td>Collecting data on substance abuse**</td>
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<tr>
<td>Collecting data on illegal risk behaviors**</td>
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<tr>
<td>Where subjects may be involved in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures)</td>
</tr>
<tr>
<td>HIV status</td>
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<td>Domestic violence</td>
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<td>Children with chronic illness</td>
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<td>Immigration status</td>
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<td>Welfare assistance</td>
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<tr>
<td>Personal information obtained from records</td>
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<tr>
<td>Reproductive health</td>
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<tr>
<td>Criminal/incarceration history</td>
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* Bolded topics are those that are listed on the NIH Certificate of Confidentiality Kiosk
** Data on substance abuse and on illegal risk behaviors are combined on the NIH Certificate of Confidentiality Kiosk. For the purposes of the study, we counted the categories as separate issues.
The Application Process.
Investigators obtained a Certificate of Confidentiality from different NIH institutes, although over half (10/19) said they had applied for a Certificate through the National Institute on Drug Abuse (NIDA) (Table 3). The median estimate by investigators of the duration of the application process was eight weeks.

Fifty-three percent of investigators (10/19) found the application process to be simple and straightforward. When asked whether they encountered any difficulties during the application process, almost half (9/19) reported no problems. Eight investigators remarked that the application process took too long, but half of them attributed the delays to their failure to use the NIH-recommended format and language. One investigator suggested that other researchers could avoid delays by precisely following the directions on the NIH Web site and treating the application process “as if it were a form and not guidelines.” The remaining delays were attributed to personnel changes at NIH (two cases) or were unexplained.

Two investigators mentioned difficulties in coordinating IRB approval and the Certificate application.

Investigators offered suggestions for how the federal government could improve the application process. Their suggestions included allowing on-line applications to improve turn around time, providing more guidance on applications for non-federally funded projects, and giving instructions about the application process in the same level of detail as for grant applications.

Five investigators also suggested that IRBs could facilitate the application process by providing more guidance and assistance about when and how to apply, model consent language for different study types, and more general guidance on how to protect participant identities. Two investigators indicated that their IRB Web site provides helpful guidance about the Certificate of Confidentiality and clear instructions about how to apply for one.

Deciding to Get a Certificate of Confidentiality.
When asked why they decided to obtain a Certificate of Confidentiality, two important themes emerged from investigators’ responses: protecting their data and reassuring participants about the confidentiality of the data (12/19).

When asked why they decided to obtain a Certificate of Confidentiality, two important themes emerged from investigators’ responses: protecting their data and reassuring participants about the confidentiality of the data.

Nine investigators explicitly discussed the need to protect their data as the reason for obtaining a Certificate of Confidentiality. For example, one investigator who was researching potentially illegal activity sought information about the Certificate of Confidentiality because she was concerned about being sued. Five investigators also discussed the desire to reassure participants as a reason for obtaining a Certificate. In addition, most of the investigators (13/19) knew about the Certificate of Confidentiality because they had previous personal experience with the Certificate or knew investigators who had obtained one.

Four investigators applied for a Certificate of Confidentiality because their IRB had recommended they do so, or in one case “demanded” that they do so. Another three investigators applied for a Certificate because their funding agency recommended one.

Certificates’ Usefulness.
Eight investigators reported that the Certificate of Confidentiality had been useful. Two investigators appear to have been successful in using the Certificate of Confidentiality to block the disclosure of information in response to a subpoena. One of these investigators had been subpoenaed to testify as a witness in a case in which confidential research data may have been relevant. The investigator informed the attorney who obtained the subpoena about the project’s Certificate of Confidentiality. When called to testify, she was not asked to disclose confidential information. The second investigator whose data was subpoenaed contacted the university legal department, which informed the subpoenaing attorney that the project had a Certificate of Confidentiality. At the time of our interview with the investigator, no further action had been taken on the subpoena. Both investigators felt that the Certificate of Confidentiality had protected them from forced disclosure. Two other investigators reported an instance when a colleague had to assert their Certificate of Confidentiality against a subpoena for data. One of these cases was successful, and the outcome of the other was unknown. In contrast, another investigator commented that he knew about a case in California where a Certificate of Confidentiality did not protect the researchers from having to disclose data pursuant to a subpoena.

The investigators we interviewed also thought the Certificate of Confidentiality was useful in reducing investigator anxiety about protecting the confidentiality of research data. As one investigator noted, “I sleep better at night.” Another investigator said it “feels good” to take extra steps to protect participants because it “would be devastating” to have her data used against research participants. Four investigators stated that a Certificate of Confidentiality...
Confidentiality may also reduce participant anxiety. Two investigators suggested that a Certificate may encourage participants to be more forthcoming and improve data reliability and validity. For example, one investigator told us that many women who receive public assistance do not want to talk about their substance abuse because they fear their children will be taken away. Accordingly, she obtained a Certificate of Confidentiality for her research “to improve the participants’ sense of safety” and to be able to tell them truthfully that “their information would go nowhere.”

Six investigators questioned whether a Certificate of Confidentiality could actually prevent data disclosure if subpoenaed, and two investigators mistakenly believed that a Certificate of Confidentiality had never been tested legally. Nevertheless, four of these investigators expressed positive opinions about the Certificate of Confidentiality. Said one, “I’m glad we have it.” However, another investigator whose IRB required him to obtain one only “assumed” that the Certificate of Confidentiality would be useful. Another researcher indicated that a Certificate was “something” useful, explaining that it was “impossible to gauge” its effect on or meaning to participants. One investigator who believed the Certificate of Confidentiality was useful to the researcher commented that he was unsure whether having one makes “a participant feel more protected, more willing to participate, or more likely to be honest.”

Another investigator said he did not think that it was essential to obtain a Certificate of Confidentiality, but that doing so had become a “tradition” in substance use research.

Only one investigator held a decidedly negative opinion about the usefulness of a Certificate of Confidentiality, calling it a “horrible hindrance.” In this case, the Certificate was obtained on the recommendation of the IRB for the final year of a longitudinal study. To compensate for the time it took to explain the Certificate of Confidentiality (plus new HIPAA privacy requirements) in the informed consent process and consent documents, the investigator shortened her interview instrument by one-third. As a result, she felt that having a Certificate of Confidentiality limited her research. Moreover, unlike the other investigators, she believed that a Certificate of Confidentiality provides a false sense of security to the participants, especially since having one does not preclude investigators from complying with state reporting requirements.

Nearly all of the investigators (17/19) said they would recommend a Certificate of Confidentiality to other investigators conducting sensitive research. Investigators recommended a Certificate for a variety of research topics where disclosure of data potentially could be harmful to research participants (Table 2). Two investigators stated that because the application process is so simple there is no reason not to apply for one.

### Consent Form

#### Requirements

The majority (12/19) of investigators said that the NIH required them to mention in their consent forms that they had a Certificate of Confidentiality or had applied for one. Six researchers also noted that the consent forms had to include language about the Certificate’s limitations: that it does not prevent participants from disclosing their personal information and that there may be legal mandatory reporting requirements (e.g., reporting child abuse or releasing information to the federal government for auditing purposes). One investigator successfully challenged the NIH’s recommended consent language. She objected to the suggested language because it sounded like “legalese” that the participants in her study, most of whom had low literacy, would be unable to understand. She also thought that language about child abuse reporting was “too harsh” and “threatening.” She negotiated these issues with an NIH representative to change the language so that it was understandable to participants and sounded less threatening. Another investigator indicated that he had concerns about the recommended informed consent language, but did not challenge it because of time pressures to proceed with interviews.

#### Participant Reactions

According to the UCSF researchers we interviewed, participants’ reactions to disclosure about the Certificate of Confidentiality varied. Three investigators stated that having a Certificate was positive for participants because it reassures them and may encourage research partici-
pation. An additional six investigators indicated that participants generally reacted favorably when the protections of a Certificate of Confidentiality were explained to them. Two investigators said that mentioning a Certificate of Confidentiality sometimes caused participants to become anxious about the confidentiality of their personal information obtained during research participation. Nevertheless, these investigators thought that discussion about a Certificate of Confidentiality focused needed attention on the issue of confidentiality. Five investigators reported no specific reactions by research participants regarding a Certificate of Confidentiality. One of these investigators said he was “willing to bet that they don’t care.” On the other hand, the investigator who obtained a Certificate of Confidentiality for a study that had been underway for several years reported that some participants disliked the additional time needed to discuss the Certificate during the informed consent process and asked, “When are we going to get to the questions?”

Discussion

Our study adds to the limited empirical evidence about investigators’ attitudes toward and experiences with the Certificate of Confidentiality. Investigators who have used a Certificate reported that the application process was simple and recommended that researchers obtain one. Investigators also said that having a Certificate of Confidentiality provided reassurance to them and to research participants that sensitive data would be protected. This finding suggests that disclosure about the Certificate of Confidentiality in the informed consent process and consent documents may not deter research participation because of concerns about confidentiality as suggested by some commentators.17 However, investigators may need to take additional time to explain the risks to and protection of confidentiality. The reassurance that a Certificate of Confidentiality provides to investigators—helping them “sleep better at night”—alone may justify its use if that means important, sensitive research that otherwise would not be conducted goes forward. Accordingly, the Certificate of Confidentiality meets the NIH’s policy goal of encouraging research on important, but sensitive, public health topics.

Our study also provides important evidence about the effectiveness of the Certificate of Confidentiality in protecting research data. Although Cooper et al., reported no additional information about how frequently investigators nationwide used a Certificate of Confidentiality to protect research data and whether having a Certificate was effective in doing so. Nevertheless, the Neuman case and the investigators’ experiences we report provide some reassurance to investigators that a Certificate of Confidentiality will protect them from being compelled to disclose sensitive data. Indeed, the experience of investigators who have been subpoenaed may be more pertinent than appellate court cases because few disagreements over subpoenas are likely to reach an appellate court.

The majority of investigators reported they were aware of the Certificate of Confidentiality before research sponsors or IRBs mentioned it to them. However, researchers who do not commonly work in sensitive areas may be less familiar with the Certificate and the protections it provides.20 Previous research indicates that program officers at the NIH already direct investigators to the NIH Certificate of Confidentiality Kiosk,21 but further outreach may be helpful.22 For example, the NIH and IRBs could give all new investigators information about the Certificate of Confidentiality, including the link to the NIH kiosk.

Although nearly all of the UCSF researchers reported positive experiences with the Certificate of Confidentiality, the experiences of two investigators suggest problems with the time required to obtain one and the NIH template language to describe the Certificate to participants. One investigator, working in a primary care setting, had to remove questions from the interview because of the time it took to explain the Certificate of Confidentiality to participants. The added protections of a Certificate of Confidentiality should not come at the expense of the research. Another researcher we interviewed successfully persuaded the NIH and her IRB to accept alter-
nate, simplified language that was more accessible to her research participants. A simplified disclosure about the Certificate of Confidentiality might improve participant understanding, while also reducing the burden on the research study. The NIH might develop simplified language that investigators and IRBs can accept.

Our study had several limitations. Because this was an exploratory study, we interviewed a limited number of investigators. All of these investigators were from one institution—UCSF—and all had experience with the Certificate of Confidentiality. Other researchers have found that use of a Certificate of Confidentiality may be congregated within an institution and among particular investigators. Accordingly, the investigators’ experiences in our study may not reflect those of other investigators at other institutions.

In deciding whether to request a Certificate of Confidentiality, researchers and IRBs should consider the effect involuntary disclosure of data might have on research participants. In cases where the impact is minimal, such as when participants already have been diagnosed with a genetic disease, the additional protection of a Certificate of Confidentiality may be unnecessary. However, in research where investigators ask about illegal behaviors, the additional protection of a Certificate of Confidentiality may be crucial to the study and to participant protection.

References
3. 45 CFR 46.111.
Research Participant Safety and Systems Factors in General Clinical Research Centers

Reports suggesting that many patients are injured because of their medical care have transformed patient safety into a major public health focus.¹ Research into the contributors to medical errors and patient injuries has identified important and common system failures.² One definition describes a system as "a collection of interdependent elements that interact to achieve a common purpose."³ In clinical medicine, this would include healthcare system elements relevant to patient care. These include everything from emergency rooms to ambulatory clinics, laboratory services, and hospital services. Qualitative research in non-medical industries such as aviation and nuclear power reveals that organizational factors such as poor communication, inadequate training, and excess workloads appear to produce environments that facilitate human errors.⁴ A systems approach towards organizational safety steers away from blaming a single individual and looks to identify and correct other organizational factors that might have triggered an adverse event.⁵

Clinical research shares many features with clinical medicine. In both situations, patients or participants may be exposed to high-risk procedures or medications. For example, both research participants and clinical patients undergo similar routine procedures, such as the insertion of an intravenous or Foley catheter. Identifying toxicities or side effects requires use of similar monitoring procedures, whether in the research or clinical context. Just as with clinical medicine, system failures likely exist within clinical research⁶ and might result in adverse outcomes.⁷ One salient example comes from the case involving the tragic death of Ellen Roche, a research subject in a study conducted at Johns Hopkins University.⁸ During the time period in which Ms. Roche was a research participant, protocols submitted to the university's Institutional Review Board (IRB) were only formally discussed by a subcommittee of the IRB, rather than by the full review board. An external committee that reviewed the Roche incident noted that the subcommittee review "system limits, by its design, active discussion by the full committee, and loses the expertise that committee members bring to the review" of research protocols.⁹ These communication deficiencies, as well as other organizational cultural factors, were highlighted as significant contributors to the tragedy.

Unlike the many reports emerging from clinical medicine, few data exist that describe research participant safety concerns. Most empirical research on the quality of clinical research has focused on important ethical concerns and participant understanding of informed consent.¹⁰ To begin to address questions about patient safety issues in clinical research, we conducted an anonymous, nationwide survey of General Clinical Research Center (GCRC) staff nurses. They were asked to report their observations on research participant safety concerns and to determine if system failures, such as poor communication or lack of training, might be present within clinical research.

Study Methods and Design

We identified 97 GCRCs from the Web site of the National Center for Research Resources (NCRR) and contacted the nurse manager listed for each GCRC. We had no response from three nurse managers and four nurse managers declined on behalf of their institution to participate in the study. From the remaining 90 GCRCs, 902 staff nurses were identified. Our initial study protocol intended to collect the names and direct mailing information for each GCRC's staff nurse; yet, most (82%) GCRC nurse managers contacted requested that we send them a packet of surveys for distribution due to concerns about confidentiality and privacy of staff. As a result, surveys were distributed either through 1) a pre-specified number of packets mailed to each nurse manager, or 2) direct mailing to nursing staff. The Vanderbilt University IRB reviewed and approved the study.

A multidisciplinary team of clinical researchers, ethicists, nurses, and patient safety advocates developed the content of the survey. The questionnaire was pilot tested for comprehension and appropriateness in two focus groups with questions removed, added or clarified based on focus group suggestions. The final questionnaire included 77 items which covered various research-related domains including informed consent, subject recruitment, adverse events, protocol deviations, research-related injuries and research-related processes.

This article focuses specifically on the questions regarding adverse events, protocol deviations, research-related injuries and research-related processes. Respondents completed nine yes/no questions regarding adverse events or study processes during the preceding six months. We also asked respondents to indicate their level of agreement with 13 specific statements using a six-point Likert scale ("strongly disagree," "disagree," "somewhat disagree," "somewhat agree," "agree," and "strongly agree"). Respondents rated the frequency of witnessed occurrences over the previous six months for seven scenarios using a five-point Likert scale ("never," "rarely," "sometimes," "often," and "very often"). Participants were instructed in three questions to rate the percentage of research subjects who had experienced an adverse event or research-related injury in the prior six months.

The cover page of the survey included definitions for serious adverse events, defined as "any untoward medical occurrence that a) results in death, b) is life-threatening, c) requires inpatient hospitalization, d) results in persistent or significant disability/incapacity, or e) is a congenital anomaly/birth defect," and defined an injury as "an act that damages or hurts."

Summary statistics are presented as proportions. For questions concerning a respondent's agreement with a particular statement, responses were dichotomized with "strongly agree," "agree," and "somewhat agree" being recoded as agree and the remaining responses being recoded as disagree. Frequency questions were categorized into either often (combining the "often" and "very often" responses), "sometimes," or "not often" (combining the "never" and "rarely" responses). All statistical calculations were performed on SAS v8 statistical software.

Results

A total of 80 out of 90 (89%) GCRC's; 433 completed surveys were returned from a total of 902 GCRC staff nurses, giving the survey an overall response rate of 48%. Most nurses were female (94%), over 40 years of age (75%) and had greater than four years of clinical research experience (58%). Sixty-three percent of GCRC staff nurses reported having ever participated as a research subject. Of 259 nurses who had also volunteered as research participants, 3% reported sustaining a research-related injury secondary to their participation.
Protocol Deviations and Adverse Events. Fifteen percent of nurses reported that they had assisted on a study in which they believed a protocol deviation occurred that could have resulted in an injury or a serious adverse event (Table 1). Two percent reported witnessing a protocol deviation that resulted in an injury. When asked to rate their perceptions regarding the frequency of certain safety concerns, 15% of nurses said they believed that protocol violations often or very often impacted research participant safety, and 6% said they believed that protocol violations often or very often resulted in injuries (Figure 1). Seven percent of nurses reported that a protocol deviation occurred which they believed was not reported to the IRB. In addition, 2% were aware of a serious adverse event occurring that they believed had not been reported to the IRB (Table 1).

Most nurses (65%) had assisted on protocols in which a research participant experienced an anticipated adverse event. Forty-two percent reported assisting on a protocol in which an unanticipated adverse event occurred and 32% reported assisting on a protocol in which a research-related injury had occurred. For individuals who reported witnessing a research-related injury occurring to a participant in the prior six months, 84% said that the injury was never or rarely severe and 97% reported that the injury was never or rarely life-threatening (Table 3).

Systems Issues. Eighty-three percent of respondents believed they had good communication with investigators regarding safety issues and 97% noted they were encouraged to contact investigators for help. Almost all of the nurses felt comfortable asking another nurse for help and 96% felt comfortable asking an investigator for help (Table 2).

Thirty-six percent of nurses believed that better staffing could help prevent unanticipated adverse events from happening. Ninety-seven percent said they had generally been provided with the necessary training to provide safe care for research participants; 81% said they were often or very often provided in-service training on study protocols. Twenty-one percent of nurses agreed with the statement that they had been given so much work to do that it negatively influenced research subject safety (Table 1).

Eleven percent of nurses noted being made to feel uncomfortable for reporting a protocol violation to an investigator and 7% reported being made to feel uncomfortable for reporting a serious adverse event. Twelve percent of nurses agreed with the statement that they would get in trouble if they refused to carry out a protocol because they had identified a problem with a participant's understanding of a study (Table 2).

Nurses who had participated as a research subject (n=251) were more likely to have assisted on a study involving a protocol violation that they believed had not been reported to the IRB compared to nurses who had never been a research subject (n=143) (9.3% vs. 3.4%, p-value = 0.03). Moreover, nurses who had previously been a research subject were more likely to have contacted an investigator regarding a protocol violation and to have refused to carry out protocol activities when there was an apparent violation than nurses with no prior experience as a research subject (30.6% vs. 20.3%, p-value = 0.02 and 13.6% vs. 6.8%, p-value = 0.03, respectively). Nurses with prior experiences as
research subjects were also more likely to report being made to feel uncomfortable about reporting either a protocol violation or an adverse event to an investigator than nurses who had never participated in a clinical study (13.2% vs. 5.4%, p-value = 0.01 and 9.3% vs. 3.4%, p-value = 0.03, respectively).

Conclusions

A comprehensive human research protection program requires ethically sound participant-investigator interactions, ongoing safety monitoring, and quality improvement and compliance. While research has accumulated detailing the deficiencies of the informed consent process as well as potential methods to improve human subject comprehension, much less data exist on clinical research safety. GCRC staff nurses who interact with research subjects throughout multiple different aspects of clinical research are ideally situated to offer a broad perspective on human subjects’ protection.

Based on our survey data, problems related to protocol deviations and research-related injuries appear common. One in six nurses had witnessed protocol deviations that they believed had the potential to result in injury. However, very few nurses were aware of a protocol violation that actually resulted in a participant injury. Approximately one-third of the respondents had reported a subject being injured because of research participation; fortunately, these injuries were rarely severe or life threatening.

Studies documenting patient safety problems in clinical medicine have often identified organizational or system failures as important contributors to adverse occurrences. In one study, 5% of medication errors were thought to be secondary to issues of poor communication. In our survey, over 95% of nurses were encouraged to contact investigators and felt comfortable doing so, although a smaller proportion (82%), believed they had good communication with investigators. Our respondents believed that they had received adequate training to conduct research safely. About a third, however, believed that better training could reduce some adverse events.

Workload and its relationship to medical errors has become the recent focus of intense investigation. Most studies find an association between nurse staffing levels (a surrogate for workload) and adverse events. One study noted that for each additional patient per nurse the odds of dying within 30 days of admission increased by 7%. In our study about one in five nurses reported that at times their workload negatively impacted research participant safety.

Another important contributor towards clinical patient safety is organizational culture. Many safety experts recommend that organizations adopt cultures of safety, which involve encouraging employees to report

<table>
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<tr>
<th>Question</th>
<th>Total/ Percent responding “Yes”</th>
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<tr>
<td>Refused to carry out a protocol due to a protocol violation?</td>
<td>11.2% (48/428)</td>
</tr>
<tr>
<td>Ever been made to feel uncomfortable for reporting a protocol violation</td>
<td>10.8% (46/428)</td>
</tr>
<tr>
<td>Ever been made to feel uncomfortable for reporting an adverse event</td>
<td>7.2% (31/430)</td>
</tr>
<tr>
<td>Have you contacted an investigator regarding a protocol violation?</td>
<td>27% (116/429)</td>
</tr>
<tr>
<td>Are there individuals or groups at my institution that I can express</td>
<td>95.6% (411/430)</td>
</tr>
<tr>
<td>my concerns to if I have a worry about research safety?</td>
<td></td>
</tr>
<tr>
<td>I have good communication with investigators regarding research</td>
<td>82.9% (353/426)</td>
</tr>
<tr>
<td>participant safety issues</td>
<td></td>
</tr>
<tr>
<td>I feel comfortable asking another staff nurse for help</td>
<td>99.5% (422/424)</td>
</tr>
<tr>
<td>I feel comfortable asking investigators for help</td>
<td>95.5% (407/426)</td>
</tr>
<tr>
<td>I am encouraged to contact investigators if I have a question</td>
<td>96.5% (409/426)</td>
</tr>
<tr>
<td>I will get in trouble if I refuse to carry out a protocol because I</td>
<td>11.5% (49/426)</td>
</tr>
<tr>
<td>identify a problem with a participant’s understanding of the study</td>
<td></td>
</tr>
<tr>
<td>Most research safety concerns that I encounter I resolve on my own</td>
<td>45.4% (194/427)</td>
</tr>
</tbody>
</table>
Table 3.
Respondents' Beliefs Regarding Protocol Deviations, Adverse Events, and Research Related Injury

<table>
<thead>
<tr>
<th>Question</th>
<th>Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over the last 6 months, what percentage of research participants in protocols that you have assisted on experienced an anticipated adverse event (known complication)?</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>21% [87/414]</td>
</tr>
<tr>
<td>Fewer than 1 in 100</td>
<td>11% [47/414]</td>
</tr>
<tr>
<td>1 in 100</td>
<td>25% [102/414]</td>
</tr>
<tr>
<td>1 in 100</td>
<td>29% [120/414]</td>
</tr>
<tr>
<td>Don't Know</td>
<td>14% [58/414]</td>
</tr>
<tr>
<td>Over the last 6 months, what percentage of research participants in protocols that you have assisted on experienced an unanticipated adverse event?</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>42% [173/415]</td>
</tr>
<tr>
<td>Fewer than 1 in 100</td>
<td>19% [78/415]</td>
</tr>
<tr>
<td>1 in 100</td>
<td>13% [53/415]</td>
</tr>
<tr>
<td>1 in 100</td>
<td>10% [40/415]</td>
</tr>
<tr>
<td>Don't Know</td>
<td>17% [71/415]</td>
</tr>
<tr>
<td>Over the last 6 months, what percentage of research participants in protocols that you have assisted on experienced a research-related injury?</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>52% [217/414]</td>
</tr>
<tr>
<td>Fewer than 1 in 100</td>
<td>17% [71/414]</td>
</tr>
<tr>
<td>1 in 100</td>
<td>8% [33/414]</td>
</tr>
<tr>
<td>1 in 100</td>
<td>7% [28/414]</td>
</tr>
<tr>
<td>Don't Know</td>
<td>16% [65/414]</td>
</tr>
<tr>
<td>Of the research participants that you have witnessed experiencing a research-related injury how often would you consider this injury severe?*</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>12% [16/132]</td>
</tr>
<tr>
<td>Rarely</td>
<td>72% [95/132]</td>
</tr>
<tr>
<td>Sometimes</td>
<td>14% [19/132]</td>
</tr>
<tr>
<td>Often or Very Often</td>
<td>0.8% [1/132]</td>
</tr>
<tr>
<td>Do Not Know</td>
<td>0.8% [1/132]</td>
</tr>
<tr>
<td>Of the research participants that you have witnessed experiencing a research-related injury how often would you consider this injury to be life-threatening?*</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>41% [55/132]</td>
</tr>
<tr>
<td>Rarely</td>
<td>56% [74/132]</td>
</tr>
<tr>
<td>Sometimes</td>
<td>1.5% [2/132]</td>
</tr>
<tr>
<td>Often or Very Often</td>
<td>0.8% [1/132]</td>
</tr>
<tr>
<td>Do Not Know</td>
<td>0.8% [1/132]</td>
</tr>
</tbody>
</table>

*Denominator only includes respondents who specifically mentioned that they have witnessed a research related injury over the prior 6 months (N = 132)

In our study, about one in 10 nurses reported being made to feel uncomfortable about reporting a protocol violation; 12% reported that they might "get in trouble" if they refused to carry out a protocol due to safety concerns.

Medical progress depends heavily on clinical research, yet studies of human subject protection compliance have been few. Major reports issued from such bodies as the National Bioethics Advisory Commission, the United States General Accounting Office, and the Institute of Medicine (IOM) have based their recommendations on case reports of research-related injuries and audits of IRB policies and procedures. These recommendations have typically called for a major restructuring of human subjects’ protection in clinical research although the recent IOM report underscored the need for more research on participant safety before significant improvements in human subjects protection can be made.

Gathering data on research safety problems poses challenges. IRBs collect investigator-reported data about adverse events and significant protocol deviations, but they are limited in their ability to monitor day-to-day operational problems associated with conducting clinical research. Furthermore, the volume of work that most IRBs must currently perform would make it challenging to adopt additional duties.

System failures that impact human subject protection programs might therefore be better identified through individuals who are involved in multiple protocols, such as staff nurses in a research unit or research ombudsmen. A notable example of the latter is the Research Safety Advocate (RSA) program developed by NCRR. This program has designated funding for specific individuals to serve as safety officers for individual
GCRCs. Although this program is still in its infancy, several survey respondents specifically singled out the RSA as a positive factor in improving human subject protection on their unit.

Our study has several limitations. First, the overall response rate was low. Because of our survey distribution method we do not know if the reason that some GCRCs did not return any surveys was a result of all of the staff nurses deciding not to participate or the nurse manager deciding not to distribute the survey. Nevertheless, 48% of nurses responded and our overall sample was large. Second, the survey relied on self-reported problems identified by nurses. Staff nurses who believed a protocol violation or adverse event was not reported to the IRB may not have been aware of such a report. Third, as research-related injuries and adverse events are not necessarily mutually exclusive occurrences, it is possible that some respondents may be reporting the same event as both categories. Finally, rates of reported injuries or research-related problems could be inflated if several nurses from the same center reported the same event.

Despite these limitations, research nurses report that protocol violations and research-related injuries do exist but very rarely result in serious injuries. Most GCRC nurses reported good communications with investigators and a willingness to ask for help if needed. Few nurses reported pressures not to report problems or inadequate training. However, system failures such as those reported within clinical medicine also exist within clinical research and might adversely impact research subject safety. The call for improving organizational culture and patient safety also applies to the research centers of many hospitals.

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References

9. See ref. 6, Steinbrook 2002.


13. Wendler D. Can we ensure that all research subjects give valid consent? Archives of Internal Medicine 2004;164(20):2201-2204.


15. See ref. 2, Leape et al. 1995.


17. See ref. 16, Aiken et al. 2002.


20. See ref. 6, Kahn and Mastroianni 2001.


Learning How to Learn: A Review of The Ethics and Regulation of Research with Human Subjects

When I first started teaching medical students, I thought I had the inside track on the best source of bioethics course materials there is: legal casebooks. The casebook is a unique textbook form, composed of selections from original works (from extensive quotations to snippets), and synopses of and citations to additional materials—all woven together with extensive, elaborate, and pointed notes and questions directing students to read critically and probe further. Although all law school casebooks are eclectic, not many are exciting. However, casebooks addressing the intersections of law, science, policy, health care, and ethics have become increasingly popular in the last 30 years, and have always been remarkably interesting and thought-provoking sources of diverse, multidisciplinary information and ideas.

I always figured that my access to health law and bioethics casebooks gave me a teaching advantage in a non-law-school setting. But now the secret is out, and I’m glad, because the casebook that officially opens the door to non-law-school uses is a quintessentially good one that fills a much-needed gap. In their preface to The Ethics and Regulation of Research with Human Subjects, authors Carl Coleman, Jerry Menikoff, Jesse Goldner and Nancy Dubler describe the book as “a variation of the traditional law school ‘casebook,’ . . . designed to foster critical thinking about the subject matter involved.” They have specifically designed the casebook to be accessible to students in law, medicine, nursing, public health, and health administration, recognizing that students in these fields may go on to be “tomorrow’s advisors, managers, and regulators of research and research institutions.” People in those roles—not to mention clinicians and researchers—need some familiarity with a wide range of issues, literatures, and disciplinary languages pertaining to research with human subjects. This casebook is the ideal way to gain that familiarity.

No casebook can ever be exhaustive. On the first day of law school, my contracts professor famously said, “I know a lot of law—and I know where to go to find a lot more.” What makes a good casebook is both what it gives you and where it points you. Research ethics and research regulation are areas in which knowing how to read, search for, compare, and keep up with information are vital. And although law students spend at least some time learning how to be intellectually adventurous without becoming an expert, health professional students often have fewer opportunities to develop and practice that approach to knowledge. This casebook shows readers how to do just that.

The book’s 17 chapters are divided into three parts: 1) background and context, and 2) general considerations in reviewing research proposals, followed by 3) special considerations. The first part is a remarkably non-boring tour through the history of human subjects research and guide to the regulatory players and their roles. Famous cases and classic articles are highlighted, but a good amount of space is devoted to good new literature and less-well-trodden territory, including examining sources of research funding and distinguishing research from similar activities (e.g., innovation, QI, and public health). This part closes with chapters on Institutional Review Boards (IRBs) and conflicts of interest that are surprisingly rich, considering the potential density of the topics.

Part two of the volume examines the basics of what IRBs do: risk-benefit assessment, informed consent, subject recruitment, justice, confidentiality, study monitoring, and injury compensation. Part three adds special populations considerations: children, adults without decisional capacity, prisoners, fetuses and embryos (including stem cell research and cloning), and close with an extensive consideration of genetic research, from specimen collection to gene transfer. Finally, much like other casebooks, the volume provides not just a standard index but an extensive set of additional finding aids, as well as appendices of federal regulatory materials and important research ethics documents.

Overall, the materials provided in this casebook admirably reflect the substantial breadth and depth of scholarly and practical experience these authors have brought to bear in its assembly. This is a really user-friendly collection that will be interesting and satisfying for both teachers and students from all the areas and disciplines the authors seek to reach. The chapter on confidentiality, an important but fairly unexciting concept, provides a good example: its 30 easy-to-digest trade paperback-sized pages provide a range of discussions of confidentiality as an ethical principle; discuss state and federal law on privacy and confidentiality; examine federal research regulations and IRB guidance documents on sensitive data and medical records review; review certificates of confidentiality; and close with the complexities of HIPAA. This is by no means too much for any reader, rigor-
ous enough for the most serious, and most important, knits together the ethical issues and their regulatory implementation, working nicely against the misguided trend of separating “ethics” from “compliance” in human research oversight.

The only problem with a casebook in this area is not of their making: the ethics and regulation of human subjects research is a swiftly moving target, and updating this work is going to be a considerable chore. However, nobody who uses this casebook should feel the need to sit around waiting for the update. If you’ve learned what you should by using it, you’ll know some important things, and you’ll know just how to go out and learn some more.

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