### Non-Compliance

#### Compromises
- Rights or Welfare of Subjects
- Integrity or Interpretability of the data

#### Serious
- A flagrant violation of the specific requirements of
  - IRB
  - NUSPP policy
  - State laws
  - Federal regulations

#### Continuing
- Repeated acts of non-compliance
  - Characterized by frequency rather than magnitude
  - There appears to be a pattern
  - Lack of understanding or attention to the safeguarding of human subjects
  - IRB has identified the problem previously, completed analysis, and provided notification

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<table>
<thead>
<tr>
<th>When Assigning Corrective Action: <strong>WHO? WHAT? WHEN?</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assignment</strong></td>
</tr>
<tr>
<td><strong>Audit</strong></td>
</tr>
<tr>
<td>usually triggered by: Subject Complaint, Employee complaint, Whistle blower, IRB request due to new information affecting rights and welfare of subjects</td>
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<tr>
<td><strong>Post-Approval Monitoring</strong></td>
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<tr>
<td>a routine compliance review of the study documents and/or observation of the consent process</td>
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<td><strong>For-Cause Training</strong></td>
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<td><strong>ALL</strong></td>
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Killing a Patient to Save His Life

By KATE MURPHY  JUNE 9, 2014

PITTSBURGH — Trauma patients arriving at an emergency room here after sustaining a gunshot or knife wound may find themselves enrolled in a startling medical experiment.

Surgeons will drain their blood and replace it with freezing saltwater. Without heartbeat and brain activity, the patients will be clinically dead.

And then the surgeons will try to save their lives.

Researchers at the University of Pittsburgh Medical Center have begun a clinical trial that pushes the boundaries of conventional surgery — and, some say, medical ethics.

By inducing hypothermia and slowing metabolism in dying patients, doctors hope to buy valuable time in which to mend the victims’ wounds.

But scientists have never tried anything like this in humans, and the unconscious patients will not be able to consent to the procedure. Indeed, the medical center has been providing free bracelets to be worn by skittish citizens here who do not want to participate should they somehow wind up in the E.R.

“This is ‘Star Wars’ stuff,” said Dr. Thomas M. Scalea, a trauma specialist at the University of Maryland. “If you told people we would be doing this a few years ago, they’d tell you to stop smoking whatever you’re smoking, because you’ve clearly lost your mind.”

Submerged in a frozen lake or stowed away in the wheel well of a jumbo jet at 38,000 feet, people can survive for hours with little or no oxygen if their bodies are kept cold. In the 1960s, surgeons in Siberia began putting babies in snow banks before heart surgery to improve their chances of survival.

Patients are routinely cooled before surgical procedures that involve stopping the heart. But so-called therapeutic hypothermia has never been tried in patients
in which a penetrative wound has already occurred, and until now doctors have never tried to replace a patient’s blood entirely with cold saltwater.

In their trial, funded by the Department of Defense, doctors at the University of Pittsburgh Medical Center will be performing the procedure only on patients who arrive at the E.R. with “catastrophic penetrating trauma” and who have lost so much blood that they have gone into cardiac arrest.

At normal body temperatures, surgeons typically have less than five minutes to restore blood flow before brain damage occurs.

“In these situations, less than one in 10 survive,” said Dr. Samuel A. Tisherman, the lead researcher of the study. “We want to give people better odds.”

Dr. Tisherman and his team will insert a tube called a cannula into the patient’s aorta, flushing the circulatory system with a cold saline solution until body temperature falls to 50 degrees Fahrenheit. As the patient enters a sort of suspended animation, without vital signs, the surgeons will have perhaps one hour to repair the injuries before brain damage occurs.

After the operation, the team will use a heart-lung bypass machine with a heat exchanger to return blood to the patient. The blood will warm the body gradually, which should circumvent injuries that can happen when tissue is suddenly subjected to oxygen after a period of deprivation.

If the procedure works, the patient’s heart should resume beating when body temperature reaches 85 to 90 degrees. But regaining consciousness may take several hours or several days.

Dr. Tisherman and his colleagues plan to try the technique on 10 subjects, then review the data, consider changes in their approach, and enroll another 10. For every patient who has the operation, there will be a control subject for comparison.

The experiment officially began in April and the surgeons predict they will see about one qualifying patient a month.

It may take a couple of years to complete the study. Citing the preliminary nature of the research, Dr. Tisherman declined to say whether he and his colleagues had already operated on a patient.

Each time they do, they will be stepping into a scientific void. Ethicists say it’s reasonable to presume most people would want to undergo the experimental
procedure when the alternative is almost certain death. But no one can be sure of the outcome.

“If this works, what they’ve done is suspended people when they are dead and then brought them back to life,” said Dr. Arthur L. Caplan, a medical ethicist at New York University. “There’s a grave risk that they won’t bring the person back to cognitive life but in a vegetative state.”

But researchers at a number of institutions say they have perfected the technique, known as Emergency Preservation and Resuscitation, or E.P.R., in experimental surgeries on hundreds of dogs and pigs over the last decade.

As many as 90 percent of the animals have survived in recent studies, most without discernible cognitive impairment — after the procedure, the dogs and pigs remembered old tricks and were able to learn new ones.

“From a scientific standpoint, we now know the nuts and bolts and that it works,” said Dr. Hasan B. Alam, chief of general surgery at the University of Michigan Medical Center, who has helped perfect the technique in pigs.

“It’s a little unsettling if you think of all the what ifs, but it’s the same every time you push into new frontiers,” he added. “You have to look at risk and balance it against benefits.”

Trauma accounts for more years of life lost than cancer and heart disease combined, and it is the leading cause of death in people up to age 44, according to the Centers for Disease Control and Prevention. Surgeons are eager for new techniques that would help better the odds in emergency situations. Black males are disproportionately victims of homicide, especially gun violence, and most of the patients likely to fit the study criteria in Pittsburgh are African-American males, according to officials at the medical center.

In order to obtain an exemption to federal informed consent rules, the hospital held two town hall meetings on the university campus, placed advertisements on buses, and made sure the news got in newspapers catering to minority readers.

Officials posted information about the study on a website, acuteccareresearch.org, and conducted a phone survey in the neighborhoods most at risk for “involuntary enrollment” in the trial. Still, a taxi driver, grocery clerk and security guard — all African-American men approached at random — said
they had never heard of the trial, though they work within a couple of miles of the hospital.

They also did not object. “I don’t have a problem with it, if it saves lives,” said Charles Miller, a 52-year-old security guard.

Just 14 people have so far requested “No E.P.R.” bracelets, according to the medical center.

Nearly a half-dozen trauma hospitals may join the trial and begin testing the hypothermia procedure on dying patients, including the University of Maryland Medical Center in Baltimore.

Dr. Scalea, who will head the effort there, said he hoped to receive final regulatory approval by the end of the year.

He recalled a recent stabbing victim who died on his operating table.

“He might have lived if we could have cooled him down,” Dr. Scalea said.

A version of this article appears in print on June 10, 2014, on page D1 of the New York edition with the headline: Killing a Patient to Save His Life.
Conducting ethical research with correctional populations: Do researchers and IRB members know the federal regulations?
Mark E Johnson, Christiane Brems, Bridget L Hanson, Staci L Corey, Gloria D Eldridge and Kristen Mitchell

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OnlineFirst Version of Record - Jul 1, 2013

What is This?
Conducting ethical research with correctional populations: Do researchers and IRB members know the federal regulations?

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Abstract
Conducting or overseeing research in correctional settings requires knowledge of specific federal rules and regulations designed to protect the rights of individuals in incarceration. To investigate the extent to which relevant groups possess this knowledge, using a 10-item questionnaire, we surveyed 885 IRB prisoner representatives, IRB members and chairs with and without experience reviewing HIV/AIDS correctional protocols, and researchers with

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and without correctional HIV/AIDS research experience. Across all groups, respondents answered 4.5 of the items correctly. Individuals who have overseen or conducted correctional research had the highest scores; however, even these groups responded correctly only to slightly more than half of the items. These findings emphasize the need for ongoing training in federal guidelines governing correctional research, particularly for those individuals who are embarking on this type of research.

**Keywords**
correctional settings, HIV/AIDS, prisoners, research ethics, vulnerable populations

**Introduction**

At 750 incarcerated persons per 100,000, the United States has the world’s highest incarceration rate (Hartney, 2006; Pew Center on the States, 2008). The United States also has the largest number of individuals incarcerated, with 2,266,800 individuals incarcerated in federal, state and local prisons in 2010, or approximately one of every 100 Americans (Pew Center on the States, 2008; U.S. Department of Justice, 2011). All told, with approximately 5 per cent of the world population, the US houses one-quarter of the world’s prisoners.

Compared to the general population, incarcerated people have higher rates of substance abuse and dependence (National Center on Addiction and Substance Abuse at Columbia University, 2010), HIV/AIDS and other communicable diseases (Hammett et al., 2002; Maruschak, 2012; US Department of Justice, 2009), and psychiatric disorders (Boone, 1995; Teplin, 1994; Teplin et al., 1996; Veysey and Bichler-Robertson, 2002). These public health issues are further compounded by poverty, low educational levels, and lack of resources and services in the community before and after release. A continuous stream of individuals enter custody and are released every year, resulting in approximately 7 million releases annually (Hammett et al., 2002; Rapposelli et al., 2002), and incarcerated individuals bring existing problems back into their communities upon release (Centers for Disease Control and Prevention, 2001; Leh, 1999).

Given the many public health issues and their impact on the general population, correctional settings have considerable potential for meaningful and beneficial research. However, the history of prisoner research is rife with examples of abuse. Although the more egregious violations of prisoners’ rights have been reported in other countries, violations of prisoners’ rights have also occurred in the US. Examples of these violations include testing drugs without proper consent and using inducements (e.g. food and medical care) that may be coercive for individuals in correctional settings (Dubler and Sidel, 1989; Hammett and Dubler, 1990; Lazzariní and Altice, 2000). Intentional and unintentional abuses are possible considering that prisoners, compared to the general population: have greater potential
for limited ability to provide informed consent; present with increased likelihood for impaired ability to understand risks, benefits, and harms of research participation; and are more readily denied access to the benefits of research. Given these vulnerabilities for incarcerated people, additional federal rules and regulations were instituted to provide extra safeguards for the protection of prisoners as research participants (Institute of Medicine, 2006).

The purpose of this study was to determine the degree to which individuals conducting or overseeing research in correctional settings are knowledgeable about the special rules and regulations developed to protect prisoners who serve as research participants. To accomplish this, we conducted a survey with HIV/AIDS researchers and IRB chairs, members, and prisoner representatives.

**Method**

**Participants**

Participants were selected from among five nationwide population pools: (i) researchers who conducted HIV/AIDS research in correctional settings; (ii) researchers who conducted HIV/AIDS research in non-correctional settings; (iii) IRB chairs and members who reviewed HIV/AIDS research protocols in correctional settings; (iv) IRB prisoner representatives; and (v) IRB chairs and members who reviewed HIV/AIDS research protocols in non-correctional settings. To identify correctional HIV/AIDS researchers, we searched electronic databases for recent research funding, scientific literature, and convention presentations using specific search terms to identify HIV/AIDS research studies conducted with adult correctional populations in the US. To identify non-correctional HIV/AIDS researchers, we searched electronic databases for scientific literature using specific search terms and delimiters to identify non-correctional HIV/AIDS research studies conducted with adults in the US. From these searches, we retained authors who had two or more HIV/AIDS-related publications since 2000, from whom we randomly selected potential participants. To identify IRB chairs, members, and prisoner representatives, we obtained a listing of all federally recognized IRBs from the Office of Human Research Protections (OHRP). From this listing, we selected the IRBs associated with our sample of correctional researchers as well as a random sample of 570 additional IRBs. For as many of these IRBs as possible, we obtained contact information for all chairs, members, and prisoner representatives. To identify prisoner representatives, in addition to those selected through the IRB search, we selected all remaining individuals included on a separate OHRP listing of prisoner representatives. Finally, we requested individuals who participated in our survey to recommend names and contact information for individuals they believed would be eligible and interested in participating in this study. This snowball sampling yielded an additional 163 potential
participants. Contact information was gathered through online sources, and potential participants were retained if this information was available.

Through these efforts, we developed a final pool of 714 correctional HIV/AIDS researchers, 702 non-correctional HIV/AIDS researchers, 388 correctional IRB chairs and members, 1529 non-correctional chairs and members, and 268 prisoner representatives. Based on initial contacts, 1055 names of potential participants were removed because of having undeliverable addresses, or being deceased or retired, leaving a final sample of 2546. Of these 2546 individuals, 948 participated by completing our survey, for an overall response rate of just over 37 percent. Of these respondents, 885 provided usable data in response to the survey section related to knowledge of rules and regulations governing correctional research. Table 1 provides the demographic characteristics of individuals who provided knowledge data.

**Instrumentation**

The survey used was developed as part of a NIDA-funded study designed to explore ethical challenges and barriers in conducting HIV/AIDS research in correctional settings. This survey consisted of 10 sections. Of interest to this article is the section on knowledge of rules and regulations governing correctional research. This section includes 10 statements (see Table 2) developed based on federal rules and regulations for overseeing biomedical and behavioral research involving prisoners (45 CFR 46, Subpart C; www.hhs.gov/humansubjects/45crf46.html). For each statement, respondents answered true, false, or unsure.

**Procedures**

After receiving approval by the University of Alaska Anchorage Institutional Review Board, survey procedures were implemented following the general recommendations of Dillman (2007). Specifically, the survey process began with a pre-letter notifying potential participants that they would soon receive an email requesting their participation in an online survey. This letter was followed two weeks later by the email consisting of a cover letter and a link to an informed consent form, payment form, survey, and non-participation form. Relying on individualized code numbers for tracking purposes, up to four reminder emails were sent at approximately two-week intervals to individuals who had completed neither a survey nor a non-participation form. A letter was mailed approximately one week prior to the last email reminder. As our final contact, to address concerns that emails may have been identified by email hosts as spam and not delivered properly, we sent a paper version of the survey to all potential participants who had yet
to complete the survey. Respondents who completed the survey received $60 compensation and had the option of entering a raffle for prizes.

### Statistical analysis

A total knowledge score was calculated for each participant by determining how many items were answered correctly. Data were included if a participant answered six or more of the 10 questions. For the 15 participants who answered at least six of the 10 items but skipped one or more item, the skipped items were scored as ‘incorrect’. Additionally, answers of ‘unsure’ were scored as ‘incorrect’. Preliminary analyses revealed that years of professional experience, educational

**Table 1.** Demographic Characteristics of Participants ($N = 885$).

<table>
<thead>
<tr>
<th>Demographic Variable</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Professional Group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correctional HIV/AIDS Researchers</td>
<td>175</td>
<td>19.8%</td>
</tr>
<tr>
<td>Non-correctional HIV/AIDS Researchers</td>
<td>131</td>
<td>14.8%</td>
</tr>
<tr>
<td>Correctional IRB Chairs or Members</td>
<td>189</td>
<td>21.3%</td>
</tr>
<tr>
<td>Non-correctional IRB Chairs or Members</td>
<td>320</td>
<td>36.2%</td>
</tr>
<tr>
<td>IRB Prisoner Representatives</td>
<td>70</td>
<td>7.9%</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>416</td>
<td>47.0%</td>
</tr>
<tr>
<td>Women</td>
<td>455</td>
<td>51.4%</td>
</tr>
<tr>
<td>Missing</td>
<td>14</td>
<td>1.6%</td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>72</td>
<td>8.1%</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>46</td>
<td>5.2%</td>
</tr>
<tr>
<td>Caucasian</td>
<td>671</td>
<td>75.9%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>39</td>
<td>4.4%</td>
</tr>
<tr>
<td>Native American</td>
<td>8</td>
<td>0.9%</td>
</tr>
<tr>
<td>Other</td>
<td>32</td>
<td>3.6%</td>
</tr>
<tr>
<td>Missing</td>
<td>17</td>
<td>1.9%</td>
</tr>
<tr>
<td><strong>Highest Level of Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than Master’s degree</td>
<td>51</td>
<td>5.8%</td>
</tr>
<tr>
<td>Master’s degree</td>
<td>131</td>
<td>14.8%</td>
</tr>
<tr>
<td>Doctoral or professional degree (including JD, PhD, MD)</td>
<td>613</td>
<td>69.2%</td>
</tr>
<tr>
<td>Missing</td>
<td>90</td>
<td>10.2%</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years</td>
<td>50.2</td>
<td>10.2</td>
</tr>
</tbody>
</table>
Table 2. Percentage of Correct Responses, by Group.

<table>
<thead>
<tr>
<th>According to current federal guidelines …</th>
<th>Prisoner Representative</th>
<th>IRB Chair/Member with Corrections</th>
<th>HIV/AIDS Researcher with Corrections</th>
<th>IRB Chair/Member without Corrections</th>
<th>HIV/AIDS Researcher</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>A non-detained individual on probation or parole in the community can be considered a prisoner (false)</td>
<td>30.7%</td>
<td>36.3%</td>
<td>24.2%</td>
<td>31.1%</td>
<td>25.1%</td>
<td>29.8%</td>
</tr>
<tr>
<td>Continuing IRB review of research protocols that are actively recruiting prisoners as participants requires the presence of a prisoner representative (true)</td>
<td>80.7%</td>
<td>86.0%</td>
<td>73.7%</td>
<td>72.1%</td>
<td>49.6%</td>
<td>72.4%</td>
</tr>
<tr>
<td>A prisoner representative on the IRB must be a prisoner or former prisoner (false)</td>
<td>82.0%</td>
<td>82.0%</td>
<td>61.3%</td>
<td>60.9%</td>
<td>37.4%</td>
<td>63.3%</td>
</tr>
<tr>
<td>If multiple IRBs are reviewing a prisoner research protocol, each IRB must have a prisoner representative (false)</td>
<td>25.6%</td>
<td>20.3%</td>
<td>23.1%</td>
<td>14.0%</td>
<td>14.1%</td>
<td>18.0%</td>
</tr>
<tr>
<td>Research involving prisoners can be reviewed via an expedited review process (true)</td>
<td>16.6%</td>
<td>14.4%</td>
<td>12.3%</td>
<td>11.7%</td>
<td>5.8%</td>
<td>11.8%</td>
</tr>
<tr>
<td>Studies with more than minimal risk to the participants can be conducted with prisoners once approved by the Office for Human Research Protections (true)</td>
<td>53.8%</td>
<td>39.3%</td>
<td>41.2%</td>
<td>38.7%</td>
<td>29.0%</td>
<td>39.0%</td>
</tr>
<tr>
<td>Prisoner research review uses a different definition of ‘minimal risk’ than research that does not include a prisoner population (true)</td>
<td>42.3%</td>
<td>40.2%</td>
<td>47.9%</td>
<td>30.0%</td>
<td>29.6%</td>
<td>36.5%</td>
</tr>
</tbody>
</table>
According to current federal guidelines …

| Studies with no treatment control groups cannot be conducted with prisoners under any circumstances (false) | 74.3% | 69.1% | 63.4% | 53.3% | 45.1% | 58.9% |
| No member of the IRB (except the IRB prisoner representative) can have any association with the correctional facilities where the research is being conducted, apart from her or his membership on the IRB (false) | 58.9% | 43.7% | 34.5% | 29.2% | 19.3% | 34.0% |
| If a research participant becomes incarcerated during the course of a study, the requirements of Subpart C are not applicable since the study is not focused on a correctional sample (e.g., participants are recruited from a drug treatment setting) (false) | 48.7% | 51.2% | 43.2% | 39.8% | 23.8% | 41.0% |

**Table 2. (Continued)**

<table>
<thead>
<tr>
<th>According to current federal guidelines ...</th>
<th>Prisoner Representative</th>
<th>IRB Chair/Member with Corrections</th>
<th>HIV/AIDS Researcher with Corrections</th>
<th>IRB Chair/Member without Corrections</th>
<th>HIV/AIDS Researcher</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Correct</td>
<td>57.3%</td>
<td>51.1%</td>
<td>47.1%</td>
<td>42.4%</td>
<td>33.1%</td>
<td>45.0%</td>
</tr>
</tbody>
</table>
level, gender, and professional setting were not significantly related to the total knowledge score. Thus, these variables were not included in further analyses. Using the total knowledge score, a one-way ANOVA was conducted with participant group as the independent variable. Significant ANOVA results were followed by Duncan’s multiple range tests to determine which groups differed significantly from one another.

**Results**

Table 2 provides the percentage of correct responses to each of the 10 knowledge items, separately by group. Across all five groups, the mean score was 4.50 (SD = 2.08). Mean score was highest for prisoner representatives ($M = 5.73, SD = 1.77$), followed by IRB chairs/members with corrections experience ($M = 5.11, SD = 1.64$), HIV/AIDS researchers with corrections experience ($M = 4.71, SD = 1.89$), IRB chairs/members without corrections experience ($M = 4.24, SD = 2.06$), and HIV/AIDS researchers without corrections experience ($M = 3.31, SD = 2.33$).

Results of the one-way ANOVA revealed a significant effect for Group, $F(4,881) = 25.31, p < .001$. Post hoc analyses using Duncan’s multiple range tests revealed that: knowledge scores for prisoner representatives were significantly higher than scores for all other groups; scores for IRB chairs/members with corrections experience and HIV/AIDS researchers with corrections experience did not differ from one another but were significantly higher than IRB chairs/members without corrections experience and HIV/AIDS researchers without corrections experience; and IRB chairs/members without corrections experience scored significantly higher than HIV/AIDS researchers without corrections experience.

**Discussion**

Results indicated that prisoner representatives, whose involvement is required for IRBs to review prisoner-related research proposals, had the highest scores among the five groups surveyed. IRB members and HIV/AIDS researchers with experience in overseeing or conducting correctional research were the next two most knowledgeable groups. The lowest-scoring groups were IRB members and researchers who reported no experience overseeing or conducting correctional research. Although these findings are not unexpected, it is noteworthy that even though they had the highest scores, the individuals required to be familiar with the guidelines for protections of prisoners as research participants still only answered approximately half of the questions correctly.

To protect the rights of individuals in incarceration, a clearly defined set of federal guidelines for research with prisoners have been developed. As knowledge of
these guidelines appears to be low even among groups directly involved in conducting or overseeing correctional research, increased educational efforts may need to be launched to teach and practically interpret these rules. In these educational efforts, it is not enough just to identify prisoners as one of several vulnerable groups; instead, more detailed information needs to be presented to ensure that the in-depth knowledge required for prison-based research is acquired by those who need it. Further, IRBs will be well-advised to develop strategies that ensure that their members have the requisite knowledge prior to conducting reviews of prisoner-related research. IRB Chairs cannot assume that just because a particular member has been through such a review previously or is a prisoner representative that she or he has the requisite in-depth knowledge that leads to correct interpretations and decision-making. Instead, IRBs need an avenue to provide and refresh this knowledge regularly and assess its acquisition and retention.

Researchers interested in beginning work in prison settings may benefit from consultation with IRB prisoner representatives and other researchers who have a history of successfully carrying out corrections-based research. When projects are moved forward to IRBs, it is important to assess if the particular IRB in question has dealt with prison-based research. If not, preliminary education may be necessary to ensure appropriate review. Members of such IRBs may benefit from consultation with IRBs who have reviewed prison research and from consultation with individuals who have served as prisoner representatives, provided they have a firm grasp on the specialized knowledge related to protections for incarcerated individuals as research participants. Appointment of a prisoner representative is, of course, required for review of a study involving incarcerated individuals, and careful choices of prisoner representative are essential to ensuring a quality review. However, merely having the ‘appropriate background and experience’ as described by the federal guidelines is insufficient; representatives must also have detailed knowledge of the guidelines. Indeed, as their IRBs may rely on them to a great degree, it is imperative that prisoner representatives have extensive and deep knowledge and clarity about the interpretation of the guidelines. The same can be said for IRB chairs.

When reviewing the findings of the current study, several limitations must be considered. First, with a response rate of approximately 37 percent, over half of the potential participants declined to participate. However, given the fact that the individuals targeted were busy professionals and that the survey took up to an hour to complete, the response rate is adequate. This is particularly true given that response rates to surveys in general have been declining for at least two decades (Tourangeau, 2004). Second, nearly 100 survey participants skipped the knowledge section of the survey. HIV/AIDS researchers without correctional experience (the group with the lowest mean score) were significantly more likely than other groups to skip the items, and IRB members with correctional experience were more likely to complete the items. This pattern of non-completion suggests
that participants who were less likely to have this knowledge were more likely to skip the items, perhaps skewing our results toward an overestimate of knowledge levels. Third, we could find no instrument that assesses knowledge of OHRP guidelines related to prison settings. Thus, we developed our own knowledge test and no reliability data are available. Further, with an overall mean score of 4.5, we cannot be certain if items selected for the knowledge survey were overly difficult or nuanced or whether knowledge truly was limited even among groups expected to have high scores. Fourth, we examined level of knowledge but did not explore whether such knowledge is related to actual ability to interpret and apply information in research design and IRB oversight. It may be that although researchers or IRB members at a given time do not know all of the specific federal guidelines, when such knowledge is required they seek it out from readily accessible resources.

Limitations notwithstanding, our findings suggest that knowledge (and perhaps practical interpretation) of OHRP guidelines needs to be augmented. This is particularly true for IRB members and researchers encountering or engaging in prison-based work given that even these groups responded correctly only to approximately 50 percent of the knowledge items. Future research should further explore the nuances of researcher and IRB member knowledge regarding prison protection regulations and the behavioral correlates of this knowledge, including the impact of knowledge on decisions to conduct or approve particular research studies, as well as researchers’ and IRB members’ metacognition regarding this important knowledge base and their actions to improve relevant knowledge when needed.

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References


University to review ethics complaint regarding two professors

In a study of privately-run prisons, funding from private prison companies was not originally stated, something the complaint argues influenced objectivity.

by JOE BRANDT | 13 JUNE 2014

Temple is investigating an ethics complaint aimed at two professors who did not originally disclose funding for their study on private-versus publicly-run prisons, which, the complaint argued, tampered with the study’s objectivity.

Erwin Blackstone and Simon Hakim, tenured economics professors who have taught at Temple since the mid-1970s, released a working paper of their study, “Cost Analysis of Public and Contractor-Operated Prisons” in April 2013.

Through May and early June of that year, the professors published op-ed pieces about the research in newspapers like the State Journal, based in Frankfort, Ky., and the Detroit Free Press, explaining the study’s conclusion that private prisons can save taxpayers money while addressing some problems with public prisons.

“We found that contractor-operated prisons generate [12 to 58 percent] in long-run savings and help relieve overcrowding without sacrificing the quality of the services,” the two wrote in the Free Press.

Alex Friedmann, managing editor of the Prison Legal News, objected to their research and filed the ethics complaint with the university. PLN is a monthly publication about criminal justice issues with about 9,000 subscribers, most of whom are incarcerated, Friedmann told The Temple News.

Friedmann said he first heard about the study in a press release from GEO Group, a private corrections company headquartered in Boca Raton, Fla.

“Once that ran across my desk, it raised some initial questions,” Friedmann said. “I asked, ‘did this receive funding from the private corrections industry?’”

After some researching, Friedmann found that the study did receive industry funding and that there was no disclosure language on the original working paper, dated April 29, 2013. After Friedmann informally complained, the professors released an updated working paper dated May 23, 2013, with a one-sentence disclosure of funding on the fourth page.

“The study received funding by members of the private corrections industry,” the sentence read.
A 28-slide PowerPoint presentation about the study, dated Feb. 10, 2014, is available on the website for the university’s Center for Competitive Government, a research organization run through the Fox School of Business and headed by Hakim.

The Center for Competitive Government was formerly called the Privatization Research Center. Hakim is registered to teach two classes in Fall 2014, Microeconomics and “The Economics and Management of Privatization.”

This PowerPoint about the study disclosed the funding on the first slide. The disclosure reads that “the authors would like to thank members of the private corrections industry for their partial funding of this project.”

Blackstone and Hakim did not respond to multiple requests for comment by The Temple News. In an interview with the Inquirer, Hakim said, “When it appears as a working paper, it is not final. It is just for review purposes. A few weeks after, we made the disclosure that it was partially funded by the private prison industry.”

Friedmann objected to the disclosure’s placement on the fourth page, he said he felt it should have been on the first. He also felt that the specific sources of funding should have been originally disclosed.

Blackstone and Hakim would not tell the Inquirer how much funding they received or from whom. The “recent grants received” section of Hakim’s Curriculum Vitae noted that he and Blackstone conducted “an analysis of state and private prisons’ costs and performance” in 2012 and 2013 with funding from the Corrections Corporation of America, GEO Group, and the Management and Training Corporation: the three-largest private corrections companies in the country.

Friedmann also argued for disclosure language in the op-ed pieces. One of the op-eds, from the State Journal, revealed that the study had received some industry funding. The Inquirer reported that Dan Liebman, an editor at the Journal, said he would not print the piece without knowing who funded the study.

Hakim told the Inquirer that the funding was disclosed in Temple’s press release on the study and that the newspapers elected not to include the disclosure. Later in the Inquirer interview, Hakim said he was not sure. “We believe we did,” Hakim said on informing the newspapers of the study’s funding source. “It’s not that important.”

Friedmann ultimately filed a formal ethics complaint against the two professors dated June 25, 2013, stating his view that the professors violated two Temple policies: a general faculty conflict of interest policy and another policy specifically concerning financial conflict of interests in research.

“Faculty members may not allow outside financial interests or relations with relatives to influence, or appear to influence, their actions and decisions as university employees,” the general policy reads.

A university spokesman said Temple will investigate the complaint this summer and will not comment since there is an ongoing investigation.

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