The National Children's Study: A Golden Opportunity to Advance the Health of Pregnant Women

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With a $3 billion investment by the federal government, the National Children's Study (NCS) recently began recruitment. The NCS is a golden—and potentially missed—opportunity to study one of the most underrepresented populations in clinical research: pregnant women.

As the nation's largest-ever study of children's health, the NCS will examine the effects of the environment on children from before birth to 21 years of age, with participants sampled primarily through women during pregnancy. Thus the NCS presents a rare opportunity to study the health of women during and after pregnancy, in addition to the health of their children.

On both moral and policy grounds, we make the case for inclusion of women's health outcomes in the NCS. (*Am J Public Health.* 2009;99:1742–1745. doi: 10.2105/AJPH.2009.165498)

THE YEAR 2009 MARKS AN important threshold for the advancement of children's health. After nearly a decade of careful planning, recruitment has begun for the pilot phase of the National Children's Study (NCS), the largest longitudinal study of children's health ever conducted in the United States. Authorized by Congress in 2000 and led by a consortium of federal agencies, including the National Institutes of Child Health and Development, the National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention, and the US Environmental Protection Agency, the NCS will examine the effects of environmental influences on more than 100 000 children, with data collected from before birth to 21 years of age. At a cost of more than $3 billion, the study aims to gather research findings that will critically inform the "basis of child health guidance, interventions, and policy for generations to come."[1]

Although the potential benefits are enormous, the NCS may also be one of the largest missed opportunities for health advancement in recent history: the opportunity to prospectively and systematically study the health of women during and following pregnancy, as well as the babies they bear.

TREATING PREGNANT WOMEN WITHOUT EVIDENCE

Many of the 4 million women who give birth each year in the United States face conditions that require medical treatment. Approximately two thirds of women are prescribed at least one medication other than a vitamin or mineral supplement during pregnancy.[2] Yet as clinicians well know, the evidence base for determining how to treat the medical conditions of pregnant women is distressingly poor. Indeed, some have argued that there is no group of patients for whom the evidence base is weaker.[3] Only a dozen medications are approved by the Food and Drug Administration for use during pregnancy, and all are for gestation- or birth-related issues such as anesthesia or nausea.[4] Any medicine taken to treat a woman's illness during pregnancy—from hypertension[5] to cancer,[6] thromboembolism[7] to asthma[8]—is used without data adequate to guide dosing, make decisions about safety, or inform differential decisions about which medicine to prescribe.

The cost of this ignorance is profound.[9] The physiological changes of pregnancy affect the metabolism and activity of medications in dramatic and often unpredictable ways. For instance, the typical 30% to 40% increase in renal blood flow during pregnancy causes some medications to be cleared at much higher rates than in nonpregnant women.[10] Increases in blood volume, decreases in gastric-emptying time, changes in the concentrations of sex hormones, alterations in liver enzymes, and the presence of a fetal–placental unit can all alter a drug's pharmacokinetic and pharmacodynamic properties in ways that can profoundly affect efficacy. For example, a recent study revealed that amoxicillin, prescribed routinely to pregnant women and recommended by the American College of Obstetricians and Gynecologists as postexposure prophylaxis for anthrax during pregnancy, may in fact be metabolized so quickly as to prevent its reaching concentrations adequate to prevent anthrax.[11] Similarly, pharmacokinetic measurements on pregnant women taking oral medication for diabetes revealed that the drug is metabolized and excreted so quickly that considerably higher doses than are currently recommended will likely be needed to treat them effectively.[12]

In the absence of reassuring data, clinicians and patients often undertreat or halt medications indicated for medical conditions that continue or emerge during pregnancy. But the failure to treat illness can also lead to significant harm to women and their fetuses—indeed, harm that easily can outweigh the possible risks that might accompany medication use. Poorly treated asthma is associated with adverse outcomes for women (preeclampsia, hemorrhage) and fetuses (growth restriction, prematurity); by contrast, women whose asthma is well controlled with medications have perinatal outcomes similar to comparable groups without asthma.[13] Untreated major depression, too, is associated with worse outcomes for the pregnant woman and her fetus than is

depression controlled with medication.[14] And when an untreated woman dies from cancer after pregnancy, neonatal health concerns are one thing, the wrenching implications of life without a mother quite another.

CHALLENGES FOR RESEARCH DURING PREGNANCY

One cause of the dearth of data is problematic enrollment practices. Despite a 1994 Institute of Medicine report recommending that pregnant women be "presumed eligible for participation in clinical studies,"[15] many institutional review boards still regard pregnancy as a near-automatic cause for exclusion, even for studies that carry virtually no risks. Federal requirements for paternal consent in some situations—in conflict with rejection of such requirements by the Institute of Medicine[15] and American College of Obstetricians and Gynecologists[16]—are an ongoing area of controversy. But a key barrier, of course, is that inclusion of pregnant women in clinical research brings with it genuine ethical complexities. It can be difficult to strike the appropriate balance between fetal protection, permissible trade-offs in maternal and fetal risks, and sound scientific methodology. Although some progress is being made with innovative study protocols, such as administration of medications immediately prior to delivery to evaluate absorbtion,[17,18] a substantial core of knowledge for the adequate treatment of pregnant women will of necessity have to come from large observational studies that do not put fetuses at any additional risk.

This is just what the NCS represents—and in dramatic form. Here we have a very large study in which pregnant women are *by design* enrolled. Of the 100 000 children to be studied, researchers aim to enroll 25% prior to conception and a cumulative 90% during the first trimester of pregnancy. In practical terms, this means that researchers will be in regular contact with more than 90 000 women throughout the course of their pregnancies. Moreover, as researchers continue to collect data on the effects of the environment on the children that are born, they will stay in touch with these women for years to come. Such a cohort would yield an estimated 4000 women with diabetes, 4000 women with pregnancy-associated hypertension, 1000 women with chronic hypertension,[19] 12 000 women with depression,[20] 1000 women whose pregnancies were conceived with assisted reproductive technologies,[21] 4000 to 8000 women with asthma,[22] and 2700 women with thyroid disease.[23]

Further, the NCS is positioned to address a range of issues regarding women's medical needs that other observational studies under way are not. The Norwegians have launched a large observational Mother and Child Cohort Study—a title reflective of its goal: "to find causes of serious diseases in mothers and children."[24] Like the NCS, this study aims to enroll 100 000 women and infant pairs. Yet available data suggest that this study, although helpful, will not address the range of health issues and outcomes that could be followed by the NCS. For instance, enrollment in the Norwegian Cohort does not start until the middle trimester (around 17 weeks' gestation): critical first-trimester health data exposures that the NCS has been so careful to include will thus not be collected. Moreover, data collection is completed when children are 6 (rather than 21) years of age. The Norwegian Cohort data will also be derived from self-administered questionnaires and linked to medical records, as well as to blood and urine samples collected at enrollment and birth. By contrast, families enrolled in the NCS will participate in a minimum of 15 in-person visits; many more communications via telephone, computer, or questionnaire; and the collection of biological specimens and environmental sampling from home, school, and other environments. The NCS also has as a signature advantage in its sampling of individuals from the geographically and otherwise diverse US population.

EXPANDING THE SCOPE OF THE NATIONAL CHILDREN'S STUDY

The NCS represents, in short, a potential wealth of information that could dramatically improve the health prospects of women—during their pregnancies and in the years after they give birth—about which we currently know precious little.

As designed, however, the NCS will miss this golden opportunity. Although the study has been refined over time to include more complete information about the health status of pregnant women and pregnancy outcomes,[25] virtually all data about pregnancy are collected only as predictors for fetal or pediatric outcomes, not as predictors for women's health itself. Pregnancy outcomes to be recorded by the NCS are limited to preterm birth and structural congenital abnormalities, including subtle variations in morphogenesis, fetal growth restriction, and pregnancy loss. Strikingly, they include no maternal health outcomes. No data are to be collected on, for example, hemorrhage, transfusion, cardiovascular events such as heart attack or stroke, or pregnancy-induced hypertension or preeclampsia, a disease that is as common as it is poorly understood.

One maternal outcome being considered for potential inclusion relates to pelvic floor disorders and their relationship to delivery—an issue that, although important, is dwarfed by the serious and urgent nature of many medical conditions that afflict pregnant women. Perhaps most notably, although the study protocol already involves blood draws, it does not include collection of any data from those samples about the pharmacokinetics and pharmacodynamics of medications—data that are fundamental to determining the safe and effective dosing of required medications. In short, although the NCS will provide important and much-needed information about the effects of maternal medication use on the health of the fetus, absent is the other side of the coin: whether the medication is safe for the woman herself, whether it is effective in treating her underlying or emergent illness, and whether decisions to forgo medication or substitute older medications compromise her health.

Clearly, expanding the NCS to include these measures would involve additional effort and costs. Already, the NCS is under serious financial pressure: given the expanded geographical and demographic size of the study and challenges inherent to cost projections over 25 years, the original $3.2 billion approved for its duration will likely not be adequate

to study all of the children's outcomes desired. Adding further outcomes without expanded appropriations would make hard decisions about priorities even more difficult. Instead, the issue should be one of additional funding. Although money is always tight, it is hard to imagine a more compelling case for expenditure than the modest expansions required to capture critical information about women's health. Given the advantages of piggybacking on the NCS and the valuable information that could result, the addition of maternal outcomes to the study would represent an enormous efficiency, especially compared with the cost of conducting a separate study focused solely on pregnant women.

Even more compelling than efficiency are issues of justice. Pregnant women have long been underrepresented in research; they and their needs have been substantially absent from social investments to advance medical knowledge.[26] It is unjust for pregnant women to continue to benefit less than the rest of us from our enormous national effort to improve health through medical research. The NCS also raises specific issues of justice, given that enrollment of pregnant women is central to the success of the study. What was already unlikely—that a separate study of similar size geared toward measuring maternal outcomes would ever be funded in the United States—is even less likely now that investment in the NCS is under way.

TOWARD FAIR INCLUSION

So, what should be done? At a minimum, we strongly urge that the study's core protocol be expanded to include two key components. First is collection of additional data, during pregnancy and around the time of birth, from the interviews and maternal chart reviews already planned as part of the study for purposes of addressing questions of maternal health in its own right. Because enrollment for the pilot phase of the study has just begun, such changes could be made before the core protocol is finalized in May 2010 without compromising sample size.

Second, we urge inclusion of opportunistic pharmacokinetic studies by taking advantage of the maternal blood draws already incorporated in the study's core protocol. Blood drawn from women already on medications can be used to garner information about how drugs are metabolized in the pregnant body, across populations and trimesters. In fact, population pharmacokinetic studies could be done with limited additional expense, requiring only documentation of timing and dosage of medication use and timing of the blood draw. Such information would, at the very least, help to guide identification of drugs requiring intensive pharmacokinetic studies. Coupled with dose efficacy studies procured from nonpregnant populations, such studies could also provide long-sought information on how to effectively dose pregnant women with severe diseases.

Data from these modest additions would represent an extraordinary opportunity to address critically important questions. These include the near-term effect on women of taking, changing, or discontinuing antihypertensive and antidepressant medications during pregnancy, as well as the safety and kinetics of new antiepileptic drugs during pregnancy (often preferred in the nonpregnant population for more effective seizure control and fewer side effects), and of unfractionated and low-molecular-weight heparin for the treatment and prevention of venous thromboembolism, for which women are at a fourfold risk during pregnancy.[27] They might even provide much-needed data about the management and outcomes of cerebrovascular events during pregnancy, for which we have only a handful of case reports.[28]

Indeed, these two efforts together—at very little additional cost—would result in a rich data set that could lead to critical improvements in the care of pregnant women. Failure to include them would be hard to justify.

Of course, more ambitious studies could lead to even more valuable data. Of particular note would be investigating the longer-term public health impact of treatment patterns and decisions on pregnant women. How do decisions to continue or forgo antidepressants during pregnancy affect psychiatric health over time? What are the long-term effects of using older drugs routinely prescribed to pregnant women instead of newer drugs now used for the nonpregnant population in treating chronic illnesses? What are the long-term effects on women of using assisted reproductive technologies? Because contact with women in the NCS will continue both for assessment of the child's health and for surveillance for subsequent pregnancies, periodic documentation of women's health outcomes at longer intervals (5, 10, 15 years) is feasible. As with all observational studies, the study design limits the variables that can be controlled; still, it is widely agreed that observational studies of such magnitude can yield invaluable information. Just as the NCS will help to define the role of a breadth of factors on children's health, it has the potential to do the same for their mothers.

These more expansive efforts would take more expansive resources. Ideally, once women's health advocates and others begin to appreciate just how much we can learn, for just how little, by adding these more ambitious outcomes to the NCS, political support and revenue streams might be forthcoming.

Whether modest or ambitious, expansion to include maternal outcomes will require additional funding. Such funding might involve creative collaboration across institutes with strong interests in specific diseases relevant to pregnancy, such as the National Heart, Lung, and Blood Institute; the National Institute of Diabetes and Digestive and Kidney Diseases; and the National Institute of Mental Health, together with the Office of Research on Women's Health. It could also involve funding from industry, foundations, and advocacy organizations. Although as many key maternal outcomes as possible should be incorporated into the core protocol, consideration should also be given to the addition of adjunct studies, which are foreseen as a part of the broader efforts to enhance the value of the NCS. If expanding the NCS in these ways will be costly, not taking advantage of the NCS will be costlier still.

The NCS is certainly one of the most exciting research endeavors of the century—both for what it promises for understanding and promoting the health of children and for the opportunity it presents to advance the health of women who will gestate and parent them. The opportunity to address maternal outcomes is a watershed

moment in the challenging history of research and treatment of illness in pregnant women. It is an opportunity we cannot afford to miss. ■

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Compensation for Incarcerated Research Participants: Diverse State Policies Suggest a New Research Agenda

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Research with prisoners is essential to understanding the incarceration experience and creating interventions to mediate its effects on individual and community health. Policies on research involving incarcerated participants can influence the extent to which researchers are able or willing to conduct prison studies. We attempted to collect data on inmate compensation policies from all 50 states, the District of Columbia, and the Federal Bureau of Prisons. We found that 44% of these jurisdictions allow compensation for inmates who participate in research, with wide variations in terms of the clarity of and ease of access to policy information. Anecdotal data suggest considerable administrative discretion in the implementation of these policies. Further study is needed on how compensation policies are formulated and enacted and their effects on research with prisoners. (*Am J Public Health.* 2009; 99:1746–1752. doi:10.2105/AJPH.2008.148726)

MORE THAN 2 MILLION PEOPLE are currently incarcerated in the United States.[1] Behavioral and social science research with prisoners is essential to understanding the incarceration experience and creating interventions and programs to mediate its effects on people's lives. Collecting data from incarcerated participants can provide public health researchers with key information on health risks inside and outside of prison and jail, including drug use, violence, mental illness, sexual behavior, HIV, hepatitis, and tuberculosis.

However, there are several challenges involved in conducting research with incarcerated participants. For instance, policies regulating inmate participation can be difficult and time consuming to navigate. Researchers must adhere to correctional facilities' safety and inmate control procedures and ensure that prisoners' confidentiality, autonomy, and right to consent to research are not violated.[2–5]

Clearly, the potential for coercion is magnified when participants are incarcerated. Federal regulations on research involving human participants designate prisoners as a "vulnerable population" and require that special protections be afforded to them.[6,7] However, state and local interpretations of these regulations vary, and researchers and institutional review boards (IRBs) are encouraged to consider the dynamics of the local environment and context when making decisions about research protocols involving human participants.[8,9]

We used the issue of compensation for individuals who volunteer to participate in behavioral or social science research while incarcerated to explore variations in prison research guidelines and the accessibility and clarity of these policies. Individuals living in the community are often compensated for their time when they participate in research. Less is known about whether and in what instances incarcerated participants can be offered remuneration. As mentioned, state and local interpretations of federal research guidelines vary, resulting in a range of different prison research regulations across the United States. Moreover, these variations are magnified by differences in administrative implementation and researchers' access to and understanding of research policies.

METHODS

We attempted to collect data on compensation policies from every US state, the District of Columbia, and the Federal Bureau of Prisons. We searched each jurisdiction's Web site for regulations regarding payments for incarcerated research participants. When we were unable to locate guidelines online, we contacted state departments of corrections or research (as applicable) via e-mail and telephone.

We also contacted a small convenience sample of researchers who study prisoners in states that permit compensation to begin to ascertain the extent to which reimbursement actually occurs. We identified these researchers by searching an academic database with the term "prison" and the name of the state. The results of this search were skimmed to locate researchers who had recently published psychosocial research articles about prisoners. We e-mailed these individuals and asked them whether their participants had been compensated. If so, we followed up with questions about the protocol approval process, negotiation of the amount and manner of compensation, and payments procedures.

RESULTS

We obtained information about compensation of incarcerated research participants from 46 states, the District of Columbia, and the Federal Bureau of Prisons. Of these 48 jurisdictions, 44% (21) allow compensation for inmates who participate in research projects (Table 1).

State Policies

In most of the states that allow compensation, the amount and type are negotiated with the state department of corrections (DOC) on a study-by-study basis when the research proposal is reviewed, and either cash or in-kind compensation is permitted. In 3 states (California, Kentucky, Massachusetts), permission to pay and payment amount, if applicable, are determined by the warden of the facility where the research will be conducted. State policies generally require that monetary payments

TABLE 1—States That Allow Compensation of Incarcerated Research Participants

State	Research Guidelines	Comments
Alabama[a]	Alabama Department of Corrections, administrative regulation 020[13]	Administrative regulation does not discuss compensation; no strict guidelines on amount or manner of compensation.
Alaska[b]	State of Alaska Department of Corrections, management information and research: research activities[14]	"Prisoners or offenders shall not receive payment of any kind in connection with a research study without the written permission of the Commissioner. Such payments shall be consistent with the legal guidelines relating to work programs conducted by the Department."
Arizona[b]	Arizona Department of Corrections, department order 203[15]	"Researchers may pay inmates for participating in research projects."
Arkansas[c]	State of Arkansas Board of Corrections, administrative regulations: research and experimentation[16]	Administrative regulation does not discuss compensation; no strict guidelines for amount or manner of compensation; proposals must be evaluated by management.
California[b,c]	State of California, California Code of Regulations: crime prevention and corrections[17]	According to regulation, researchers must provide DOC with a study proposal that includes "[a]n estimate of the inmate/parolee subjects' time needed for the project and a plan for the compensation of the inmates/parolees." The compensation amount is set at the discretion of the warden; payment is deposited into inmates' canteen account.
Colorado[a]	Colorado Department of Corrections, administrative regulation number 1400-03: research and reporting—conduct and dissemination of research and evaluation studies[18]	Administrative regulation does not discuss compensation; payment is deposited into inmates' canteen account.
Delaware[c]	State of Delaware Department of Correction, policy manual: planning, information systems, evaluation and research[19]	State is in the process of making policy manual available online; payment is deposited into inmates' canteen account.
Hawaii[a]	No written guidelines	Payment is deposited into inmates' canteen account.
Illinois[a]	Illinois Joint Committee on Administrative Rules, administrative code title 20: research and evaluation[20]	Administrative code does not discuss compensation; compensation decisions made on a case-by-case basis.
Iowa[a,c]	State of Iowa Department of Corrections, policy and procedures: information systems/research[21]	"No offender will receive compensation, remuneration, or payment of any kind in connection with a research study." Compensation may be rarely considered on a case-by-case basis (e.g., with soon-to-be-released prisoners to encourage cooperation in a research study that begins while participants are incarcerated).
Kansas[c]	Kansas Department of Corrections, internal management policy and procedures[22]	Management policy and procedures do not discuss compensation (policy found in internal document); funds are put into inmates' trust account.
Kentucky[a]	No written guidelines	Written policy is not available; all decisions are made on a case-by-case basis and must be approved by warden; payment is deposited into inmates' canteen account.
Maryland[a]	No written guidelines	No restrictions are included in statute about payment to inmate research participants indicating that compensation is allowed.
Massachusetts[b]	Massachusetts Department of Correction, code of regulations: conduct of outside social science research[23]	"No inmate who is a research subject shall receive compensation, remuneration, or payment of any kind in connection with a research study without the express permission of the Superintendent of the institution. Such payments, if approved, should be consistent with the legal guidelines relating to work research and inmate work programs conducted by the Department."
Missouri[c]	No written guidelines	Written policy is not available; compensation decisions are made on a case-by-case basis; payment is deposited into inmates' commissary account.
Oregon[c]	Oregon Department of Corrections, administrative rules: research proposals[24]	Administrative rules do not discuss compensation.
Pennsylvania[b]	Commonwealth of Pennsylvania Department of Corrections, policy statement: research activities[25]	"Researchers are not to provide compensation or other rewards to an inmate for his/her participation in research, unless special permission is granted by the RRC (Research Review Committee)."
Rhode Island[a]	No written guidelines	Compensation decisions are made on a case-by-case basis.
Vermont[a]	No written guidelines	There are no restrictions or regulations regarding compensation in statute of State Agency of Health and Human Services.

Continued

TABLE 1—*Continued*

Wisconsin[a]	State of Wisconsin Department of Corrections, executive directive 36: research program procedures[26]	"The RRC [Research Review Committee] will approve research involving offenders as subjects only if it finds that . . . possible advantages accrued to the offender through participation in the research, when compared with the general living condition, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the environment of the prison is impaired . . . [m]oney put in canteen account."
Wyoming[a]	No written guidelines	Compensation decisions are made on a case-by-case basis; Wyoming DOC must also be compensated for research done with its inmates; money is placed in institutional trust account.

Note. DOC = department of corrections.
[a]Information collected via email.
[b]Information collected via state Web site.
[c]Information collected by telephone.

for research participation be placed in the inmates' commissary account funds, which they can either spend during their incarceration or take with them when they are released. In Wyoming, researchers must compensate the DOC for research involving inmates by making a contribution to an "institutional trust account," in addition to the option of paying the actual participants.

In 56% (27) of our study jurisdictions, including the Federal Bureau of Prisons (Table 2), all forms of remuneration or compensation are categorically prohibited. The federal system, however, does allow researchers to offer participants food or nonalcoholic beverages, provided they are consumed in the study setting. We were unable to obtain data on compensation policies from officials in 4 states: Idaho, Louisiana, New Mexico, and Nevada. Multiple e-mails and telephone calls to state officials went unreturned.

We found considerable variation in the clarity of policies regarding compensation of incarcerated participants and in our ability to gather information on these policies. Fourteen states, the District of Columbia, and the Federal Bureau of Prisons post their compensation policies on the Internet, making them readily accessible to the public. The Ohio Department of Rehabilitation and Correction's Web site is an example of an extremely user-friendly and informative site that includes not only research policies and required forms but a summary of the research that has been conducted in the state's prisons.[10,11] Eighteen of the states' Web sites list e-mail addresses for the DOC personnel able to provide information about state compensation policies. In the remaining 14 states, we obtained the information by calling state personnel. Only 4 of the 32 jurisdictions that we contacted via e-mail or telephone were able to send us a written copy of their compensation policy.

Thus, our results showed that 42% of our study jurisdictions have a publicly available written policy about paying incarcerated research participants. In some states where no written policy exists (e.g., Illinois, Kentucky), correctional personnel determine whether or not to allow compensation on a case-by-case basis. In other states where no such policy exists (e.g., Florida, Maine), correctional personnel have interpreted this lack of regulatory or legislative guidance to mean that compensation is not permitted.

Experiences of Researchers

As indicated earlier, we contacted a convenience sample of 13 researchers who had recently published sociobehavioral studies involving incarcerated participants in states that allow for compensation. Although the anecdotal information about executing compensation plans gathered in our informal conversations with these researchers is certainly not generalizable, it speaks to the gray areas and variations that exist around payment to research participants who are incarcerated. The researchers' anecdotal accounts revealed that, even within jurisdictions in which compensation is permitted, it does not always occur. Their accounts also illuminated some of the issues that arise in interpreting and implementing state policies on compensation.

One issue involves administrative discretion or misunderstanding of policies on the part of researchers. Two of the researchers we contacted reported that they did not compensate inmates because payment had been prohibited, even though policies in the states where they were conducting their studies indicate that compensation is allowed in some cases. These experiences highlight the fact that compensation is not always approved in states that allow for compensation; requests are handled administratively on a study-by-study basis, and officials may decide not to authorize compensation in some or all studies. These experiences also suggest that researchers might not fully understand state policies on compensation.

The second issue is researchers' preference not to pay participants. Four of the researchers in our sample indicated that it was their own choice not to compensate prisoners. The reasons they cited included an understanding that although compensation is allowed, pursuing the payment issue might jeopardize a researcher's relationship with the state DOC and inhibit his or her access to prisoners. Researchers also expressed the sentiment that inmate participation in research is part of a larger restorative justice process, noting their belief that cash compensation is inappropriate when

TABLE 2—States and Jurisdictions That Do Not Allow Compensation of Incarcerated Research Participants

State or Jurisdiction	Research Guidelines	Comments
Connecticut[b]	State of Connecticut Department of Corrections, administrative directive 1.7, section 12[27]	"Inmate Compensation: An inmate shall not be individually compensated for participating in any research project."
District of Columbia[b]	District of Columbia Department of Corrections, program statement: management controls–research activity[28]	"Incentives may not be offered to help persuade inmate subjects to participate. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to individuals who are no longer confined in DOC custody and who are participating in authorized research being conducted by DOC employees or contractors (for example, if study of recidivism)."
Federal Bureau of Prisons[b]	Federal Bureau of Prisons, program statement number 1070.07: research[29]	"Incentives may not be offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered."
Florida[c]	No written guidelines	Compensation not permitted.
Georgia[a]	State of Georgia, Georgia code 42-1-5: use of inmate for private gain[30]	DOC interprets Georgia code 42-1-5(b) to prohibit payment. According to this code: "It shall be unlawful for a custodian of an inmate of a penal institution to use such inmate or allow such inmate to be used for any purpose resulting in private gain to any individual."
Indiana[a]	No written guidelines	Compensation not permitted.
Maine[c]	No written guidelines	Compensation not permitted.
Michigan[a,b]	Michigan Department of Corrections, policy directive: research involving corrections facilities or offenders[31]	Policy directive does not specifically discuss compensation but states that "[c]oercion of any sort shall not be allowed."
Minnesota[c]	Minnesota Department of Corrections, policy 102.100: research[32]	Research policy does not discuss compensation.
Mississippi[a]	Mississippi Department of Corrections (MDOC), research protocol SOP 10-04[33]	"MDOC staff and inmates engaged in any research activities are not entitled to gratuities or compensation of any kind."
Montana[b]	State of Montana Department of Corrections, policy directive number DOC 1.6.4: offender participation in research projects[34]	"Offenders will not be compensated, remunerated, or paid in connection with any Department approved research projects."
Nebraska[c]	Nebraska Correctional Services, administrative regulation 103.01: research[35]	Administrative regulation does not discuss compensation.
New Hampshire[c]	New Hampshire Department of Corrections, policy and procedure directive: research and external application procedures[36]	Policy and procedure directive does not discuss compensation.
New Jersey[b]	State of New Jersey, administrative code: general research provisions[37]	"Inmates shall not be permitted to receive compensation of any kind for their research participation from any agency or entity conducting a research project."
New York[b]	State of New York Department of Correctional Services, Directive 0403: research studies and surveys[38]	"No employee of the Department or inmate shall receive compensation, remuneration, or payment of any kind for participation in the research study."
North Carolina[a]	No written guidelines	Compensation not permitted.
North Dakota[a]	North Dakota Department of Corrections and Rehabilitation, policies and procedures manual: program information and research activities[39]	"No inmate shall receive compensation, remuneration or payment of any kind in connection with a research study."
Ohio[b]	State of Ohio Department of Rehabilitation and Correction, human subjects research policy 06-RES-02[40]	"Payment of any kind to inmates for their participation in research projects is not permitted."
Oklahoma[a]	Oklahoma Department of Corrections, procedures regulating research[41]	Procedures document does not discuss compensation.
South Carolina[b]	South Carolina Department of Corrections, research conducted within the SCDC[42]	"Under no circumstance will inmates be monetarily reimbursed or provided any type of financial incentive for their participation in any research project."
South Dakota[c]	No written guidelines	Compensation not permitted.
Tennessee[b]	State of Tennessee Department of Correction, administrative policies and procedures: research projects[43]	"Required components of informed consent include . . . [a]cknowledgment that no compensation of money or goods will be made to participants."

Continued

TABLE 2—*Continued*

Texas[b]	Texas Department of Criminal Justice (TDCJ), administrative directive AD-02.28: agency research[44]	Administrative directive does not discuss compensation. According to policy (available on DOC Web site): "Neither compensation nor incentives are allowed for participating in a research project. This policy applies to both offenders and staff of TDCJ. The informed consent submitted by the Principal Investigator must include this stipulation."[45]
Utah[c]	No written guidelines	Compensation not permitted.
Virginia[c]	Commonwealth of Virginia Board of Corrections, regulations for human subjects research[46]	Regulations do not discuss compensation.
Washington[b]	State of Washington Department of Corrections, policy DOC 260.050: research review and use[47]	"Offenders may volunteer for participation. . . . There will not be any reward, favor, reduction of time, or any other benefit, either written or implied, for participation in research by staff or offenders under the legal jurisdiction of the Department."
West Virginia[c]	No written guidelines	Compensation not permitted.

Note. DOC = department of corrections.
[a]Information collected by email.
[b]Information collected via state Web site.
[c]Information collected via telephone.

research participation is considered as a way for offenders to pay off their debt to society. This issue raises questions about what it means for inmates to "pay their debt to society," who determines how this debt should be paid, and how wages received for prison employment relate to this debt.

Finally, input from formerly incarcerated individuals may inform researchers' decisions about whether or not to compensate prisoners. In their article about research with prisoners, O'Brien and Bates[12] (who were not included in the sample of researchers we interviewed) indicated that they were advised by former inmates not to offer compensation.

> We discussed the idea of an incentive to participate, but on the advice of former inmates, we realized that any incentive within the prison would be seen as providing advantages that were not available to the general population and hence were potentially coercive for that reason. We did not realize that just the fact that inmates had someone to talk to (the interviewers) could be construed as a disparity owing to the lack of the consistent availability of anyone to talk to, especially someone who might be trusted not to disclose information within the prison.[12(p215)]

This explanation describes the authors' rationale for not paying participants, even though the state in which they were working allowed for such compensation. It also raises questions about the psychosocial rewards that participants accrue from taking part in research and the extent to which these rewards might be considered coercive.

According to the reports of researchers in our sample, the logistics of providing compensation to incarcerated participants can be complicated but generally run smoothly. Among the 7 researchers we surveyed who did compensate inmates, a variety of issues were raised. Although cash was the most frequent form of compensation, food was provided to participants in one case, and textbooks were donated to the prison library in another. One researcher also reported making a library donation in a state where the statute specifically prohibited any kind of "gratuity or compensation," indicating that even in jurisdictions with this type of strict guideline, there may be some degree of flexibility allowing compensation at an institutional level.

Among the 5 researchers who provided cash, compensation amounts ranged from $5 to $50. Some, but not all, of this difference in reimbursements reflected between-study variations with respect to factors such as time or effort. In 4 of these cases, deposits were made into inmates' commissary or canteen accounts, and 2 researchers also offered the option of having a money order sent to a friend or family member in the community. One policy required that the funds be set aside for the inmates until their release. For the most part, the negotiations around these payment schemes proceeded smoothly. One researcher reported a desire to compensate participants more than the $15 per 2 hours that the state permitted. Another described complications that arose when payments reached the inmates' commissary account after they had been transferred to another facility or released.

DISCUSSION AND RESEARCH AGENDA

Our results showed that, in the United States, state policies on compensation of incarcerated research participants vary widely. This diversity reflects a system of research regulations that encourages regional and local decision-making by placing authority with local IRBs with federal oversight. Our anecdotal conversations with sociobehavioral researchers who have conducted research with incarcerated individuals suggest that states' official policies reveal only part of the story: even in instances in which compensation is permitted, it may not occur owing to administrative discretion, researchers' ethical or logistical deliberations, or misinformation about different jurisdictions' policies.

Our findings also highlight the challenges involved in gathering data on states' prison research policies. Fewer than half of the jurisdictions we assessed had a written policy on compensation. As a result of the negotiations required in both written and unwritten policies and the varying

degrees of clarity and access to these regulations, researchers may be reluctant to compensate incarcerated participants or may be unaware that payment is an option.

Our data raise several research questions that could provide an enhanced understanding of the effects of participant compensation policies, and other related prison research regulations, on the research environment. First, what is the underlying rationale of state policymakers in creating these compensation policies? Are their decisions informed by their understanding of human participant protection regulations or ideas about redistributive justice (i.e., debt to society)? What other factors influence their decisions? Second, in states where compensation is permitted, what factors are weighed by correctional research departments and IRBs in making study-specific participant payment decisions? To clarify this decision-making process, case studies could be used to examine cases in which compensation to incarcerated research participants is and is not permitted. What differentiates instances in which payment is found to be reasonable from those in which it is deemed inappropriate?

Third, to what extent are prisoners being compensated for research participation? A systematic review of prison-based research published in peer-reviewed journals and interviews with study authors would provide empirical data about when and where compensation of incarcerated participants takes place. This type of analysis could also illuminate the perspectives of different investigators on the appropriateness of payment to incarcerated participants. Fourth, how do policies on prisoner compensation affect recruitment? Does the existence of compensation, or lack thereof, shape prisoners' willingness to participate in research studies?

Fifth, beyond the issue of compensation, what is the nature of researchers' experiences with state correctional research departments? Do these gatekeepers encourage or discourage prisoner research? How so? Are certain types of research more likely to be encouraged or discouraged? Sixth, does ease of accessibility to correctional research policy matter? Is there more prisoner research in states with easily accessible written policies?

Clearly, our analysis of policies regarding compensation of inmates raises more questions than it answers about both these specific policies and the operations and effects of correctional research policies in general. Understanding incarceration is central to understanding a wide range of social and health problems. Without losing sight of the specific vulnerabilities of the people who reside inside our nation's prison walls, researchers should be actively encouraged to learn from the experiences of these individuals. The ability of correctional research policies to spark or, alternatively, extinguish the interest of researchers in these topics requires further examination. ■

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Contributors

A. B. Smoyer led the data analysis and the writing of the article. K. M. Blankenship assisted with the writing and analysis and supervised the study. B. Belt collected the data and contributed to its analysis.

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