REPORT OF THE SUBPART C SUBCOMMITTEE TO SACHRP
APRIL 18, 2005

In 2003, the Subpart C Subcommittee was charged by SACHRP with reviewing the text, interpretations and practical implementation problems associated with compliance with Subpart C of 45 C.F.R 46. Meeting five times over the past two years, the Subcommittee formulated a number of recommendations, which were shared in detail with SACHRP at its meetings in July and October 2004 and January 2005. Those recommendations that were discussed and approved by SACHRP form the basis for this final report from the Subcommittee to SACHRP.

I. Introduction

The existence of Subpart C reflects the concern of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research that, in the past, prisoners had been misused by researchers in data gathering and interventional protocols. Subpart C was designed to call attention to past abuses and to prevent further abuse of this, quite literally, "captive" population. Since the enactment of Subpart C, escalations in incarceration have resulted in over two million persons in prisons, jails, detention centers and supervised community placements. The vast majority of these persons are poor, and a disproportionate percentage are people of color.

One member of the Subcommittee quoted Sister Antonia, a chaplain at a New York State woman's prison, at Bedford Hills, who stated to the New York State AIDS Advisory Council that, "[P]risoners are viewed in the United States the way slaves were viewed in the 1800s"…. 'good' people can still look at them as less than equal to other humans." The perspective, that prisoners are less than equal members of society, and are, therefore, less protected by rights than others, may reflect the biased assumptions of non-incarcerated persons but, to some extent, it also reflects reality.

Throughout the Subcommittee's discussions, there has been a question of the relationship of the Subcommittee's recommendations to existing OHRP formal guidance and to OHRP's informal but consistent advice. In all instances it will fall to DHHS Office of General Counsel to evaluate the history of the position in the light of administrative law principles. On some issues, OHRP has had consistent advice, not formal guidance, which is contradicted by some of the policy directions suggested by the Subcommittee. In such instances, administrative law would ask if the "position on the issue has been solidified"; the answer to that question would determine if the new interpretation could be considered by OHRP as a possible new component of guidance, or whether more formal rule-making processes, including publication in the Federal Register, would need to be followed in order to change an OHRP position.

It was the conclusion of the Subcommittee, on many of the issues discussed below, that *OHRP revised guidance or revised interpretations could go far, in the short*

term, to providing directive and workable rules that IRBs could and would follow, and that would also vindicate the purposes that animated the original adoption of Subpart C. It was also the decision of the Sub-committee that, in the long run, Subpart C should be rewritten to reflect the changes in the populations of incarcerated persons, the evolving nature of research and the threats to inmate health from infectious disease especially TB, HIV and Hepatitis C. This review of the philosophy and content of special regulations for incarcerated persons would also consider the increasing number of mentally ill persons in prisons and jails, the disproportionate number of persons of color, and the increased request of prisoners that they be included in, and not excluded from participation in research.

II. Review of Research with Incarcerated Populations

At the request of the Subcommittee, an OHRP intern, Ms. Courtney Storm, compiled materials listing and analyzing all prisoner research that was published and listed on PUBMED for the past two years. The Subcommittee asked that Ms. Storm undertake this search so that there would be some documentation for the range of social and biomedical research being conducted in correctional settings, even though the Subcommittee realized that the results would be limited to those studies that had resulted in professional publication. This was undertaken in the absence of any other databases of ongoing social and biomedical research in United States correctional settings, other than the Subpart C database, whose coverage is severely limited by the limits of Subpart C jurisdiction.

- Search terms: inmates, correctional, incarcerated;
- Yield was over 1000 studies;
- Selected 79 were analyzed, those that seemed to have been conducted in correctional settings;
- Much of the data is impossible to categorize;
- 63% of ongoing research is socio-behavioral research (consistent with prisoner certification letters received by OHRP)—largely substance abuse, mental illness and disease risk behaviors;
- Data base at OHRP is only two years old;
- Lack of data at OHRP and peculiarities of jurisdiction of Subpart C combine to create a meager database; and
- Much of the research in correctional settings is graduate student research of uncertain quality.

Based on this and other background study done by Ms. Storm and Subcommittee members, t*he Subcommittee regretfully concluded that there is no easily accessible listing or register of research being conducted among prisoners in federal, state and local custody. The lack of comprehensive information here makes difficult the optimal formulation of policy recommendations relating to Subpart C standards.* The Subcommittee deliberations therefore focused on the knowledge of these issues that is available, including from the experiences of the Subcommittee members themselves, OHRP staff input, and information from correctional associations and correctional health associations.

III. Who is a "prisoner" under Subpart C?

45 CFR 46.303 (c) contains the current regulatory definition of "prisoner":

> [A]ny individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial or sentencing.

This definition has been interpreted to exclude a number of categories of subjects who are in circumstances related to corrections, such as persons: released from prison to halfway houses, court adjudicated to attend non-residential treatment programs as alternative to incarceration while living in the community, and persons who have been civilly committed, all of whom have markedly restricted liberty and autonomy.

The Subcommittee noted with some alarm that for institutions that have not voluntarily extended their Federal Wide Assurances to adopt Subpart C for all prisoner protocols and in protocols in which there is no DHHS funding (for which Subpart C compliance would be required by the presence of DHHS funding), there may be no additional protections for these prisoner-subjects. The only additional protections available for these subjects would originate from Subpart A's protection of subjects "vulnerable to coercion or undue influence." Subpart A explicitly cites "prisoners" as such a group. The Subcommittee therefore noted that two categories of subjects whose status was reviewed by the Subcommittee should be covered under Subpart A: (1) those who do not meet the formal definition of "prisoner" under Subpart C but whose liberty is restricted by the civil or criminal justice system, and (2) those whose institutions, in which the relevant IRB is situated, have chosen not to extend their assurances to include Subpart C to all protocols including prisoners as subjects.

The Subcommittee suggests that the interpretation of a prisoner in Section 46.303(c) be kept as it is, that is, narrowly defined by the words of the regulations.

At the same time, OHRP should consider some additional circumstances in which liberty is so restricted that informed consent cannot be said to be voluntary (e.g. community correctional settings and halfway houses, probation and parole), and in which those in restricted custody would not be considered "prisoners," but do deserve heightened protections. The Subcommittee recommends that for all subjects for whom there is a "nexus" between their conditions of restricted liberty and the decisions of the civil or criminal justice system, research involving those subjects should be reviewed consistent with Subpart A's protections, particularly including protections under Section 46.111 (b) for subjects "vulnerable to coercion or undue influence." OHRP should consider issuing guidance on protocol that involve such persons as subjects, suggesting questions IRBs should ask and findings they should record before approving a protocol.

IV. Research Protections for the "Subsequently Incarcerated"

At the present time, Subpart C review is required for a study to proceed when any subject is a "prisoner" under the Subpart C definition. This has proved troubling for studies that have no specific connection to correctional settings but in which one or more subjects are incarcerated subsequent to enrollment and study participation. In these cases, it cannot be said that initial consent was gained under the duress of any correctional system. The Subcommittee noted that additional safeguards for "vulnerable populations," including prisoners, are required pursuant to Section 46.111(b) of Subpart A "to protect the rights and welfare of these subjects."

In October 2004, SACHRP, upon suggestion of the Subcommittee, recommended that OHRP guidance on the issue of the "subsequently incarcerated" be changed, so that:

> ***When any research subject is subsequently incarcerated, and the study has not been reviewed under Subpart C, Subpart A protections should be deemed to apply, and there must be a focused inquiry by the researcher(s) and the IRB regarding the risks and benefits to that particular subject of continuing in the protocol as a "prisoner."***
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> ***For clinical intervention protocols there should be no clear rule as to whether the subsequently incarcerated subject should or could continue in a protocol in which he or she had been enrolled while a non-prisoner. That determination should require a focused evaluation of the specific protocol and the specific circumstances of the subject. This analysis is required in any case under Subpart A, which mandates special focus on vulnerable subjects.***

The Subcommittee's related findings and recommendations included:

- In the case of a subsequently incarcerated subject, the investigator and the IRB need to determine that the subsequently incarcerated person wants to continue in the protocol.

- If the incarcerated person wishes to continue in a trial that might positively affect the inmate's health and well-being, the researcher should make efforts to do so.

- In order to conduct the trial in a correctional institution, the researcher must seek and receive authority from that institution to continue the research. Questions will need to be asked of the prison or jail authority or medical authority in regard to the feasibility of continuing the person in the study.

- Review by IRB—the degree of IRB oversight—for reviewing requests by investigators to continue subsequently incarcerated persons in a study should include these questions:

    - How might the prisoner be subjected to coercion?

    - Are violations of confidentiality likely to occur and likely to affect the prisoner negatively? Could correctional health care providers be informed of the prisoner's study participation without informing the correctional authority?
    - Are there other issues on which this prisoner, because of her status as a subject of research might be vulnerable to negative and coercive forces?
    - The answers to these and other situation-specific cases would determine whether the research could continue with this specific subject in this specific research protocol.

- An IRB may need to calculate the risk-benefit ratio in light of the conditions of confinement, *of the particular inmate,* but with the understanding that stopping a trial might also increase the risk to the inmate-subject.

- A prisoner member or consultation with a prison expert might be needed to help the IRB to create a new risk-algorithm—depending on the level of risk.

- A prisoner member or consultation with a prison expert might be needed to help the IRB to create a new risk-algorithm—depending on the level of risk.
- *OHRP did not apply Subpart C to subsequently incarcerated persons until 2003 and none of the records of the deliberations leading to that decision seems to be available. Therefore, the current OHRP position that the subsequently incarcerated are "prisoners" may not be a solidified position in administrative law, and it may be permissible to return to the earlier contrary interpretation.*

- Most protocols that have been reviewed seem to involve follow-up to social and behavioral research. If research were not allowed in these circumstances then there would be the paradoxical result that, for example in research examining the effectiveness of job training, the failures who were imprisoned would be uncounted in the overall outcome assessment.

- It would be the responsibility of the correctional medical staff to respond to an inmate's medical intake statement, if the inmate indicates that he/she is on an experimental medication, the withholding of which might be detrimental. That would be an exceptional case, for which the standard of "deliberate indifference" would likely require that the correctional medical provider initiate immediate contact with the researcher.

- In emergent situations, when it is necessary to decide whether or not the incarcerated subject could continue in the protocol, the IRB chair should be empowered to decide, taking into account that this person has suddenly come within the category of a vulnerable subject. In such circumstances, the incarceration of a subject would be treated appropriately as an unexpected adverse event in the study, perhaps requiring a protocol change, approved either through expedited or full IRB review.

- In some cases, a result of the IRB Chairperson's scrutiny might be breaking the blind of the study and suggesting to the correctional health service how to best treat this inmate, outside of a protocol.

- The standard of "deliberate indifference" (the Eighth Amendment Constitutional standard for when medical care must be provided) would probably not apply to compel a correctional institution to allow a person to continue in a clinical trial, as by definition it is not clear that there is a benefit—it is certainly not settled treatment.

The Subcommittee feels that using this approach to the subsequently incarcerated will have the effect of protecting subjects more fully than engaging in a new Subpart C analysis, and would also streamline the process of IRB review for studies affected by this issue.

V. Identification of Prisoner Representative

The Subcommittee makes the following recommendations:

OHRP guidance should be provided to assist IRBs searching for a prisoner representative and to suggest the qualifications of persons who may qualify.

Among the primary goals in selecting a prisoner representative should be:

1. ***Adequate representation of the rights and interests of prisoners;***
2. ***Particular knowledge of correctional settings, including some awareness of local conditions in which the study will be conducted; and***
3. ***Ability to express views independent from the prison administration.***

Some sources might include:

- ***Family members of prisoners***
- ***Former prisoners***
- ***People in recovery from substance addiction who have had experience as inmates in the correctional settings***
- ***Service providers who assist the correctional population, including in the release process.***

The burden of protecting prisoners in research should rest not only on the IRB, but also on investigators, who because of their presence in the correctional settings will have more awareness of actual circumstances than an IRB.

OHRP guidance should make clear that while IRBs may be a check on the system of research protections, each investigator has a duty to assure that research in correctional settings is done in an ethical manner and that informed consent and

participation by prisoners are voluntary.

The Subcommittee discussed at some length how IRBs should best fulfill the requirement that a "prisoner representative" be a member of the IRB that reviews and approves research on persons in correctional settings.

Among the issues raised were:

- Widely noted difficulty for local IRBs to identify this prisoner representative;
- All federal government IRBs should have a prisoner representative whether or not they have accepted Subpart C in their FederalWide Assurance;
- The representative should be, if possible, an ex-offender in addition to an advocate;
- This representative should not be the only "person of color" on the IRB, which is sometimes the outcome when the "community," "non-affiliate," "non-scientist" member requirement is fulfilled by the same person;
- Non-scientist members are easily marginalized; nonetheless, it is not the purview of this Subcommittee to reform the entire IRB system—suggestions for the prisoner representative need to be made in the light of the narrow focus of the Subcommittee's work;
- Members need appropriate cultural and ethnic identification and experience;
- Need experience and information about the status of local correctional associations;
- Local prison chaplains, transitional services professionals, may be able to fill this role although, some members argued, that they may in some cases represent the interests of the institution and not the interests of the inmates;
- Ex-offenders possess the experience to serve but may not have the skills to be effective;
- An employee of the system will understand the system but may not reflect the opinions that ex-offenders would more easily embrace—case managers, public information staff may have limited insight but not the insight of an ex-offender.

In summary, the Subcommittee settled on the following as policy directions for OHRP on defining "prisoner representative" under Subpart C:

- Use functional (and not pure "status") criteria for the prisoner representative — the member needs to understand and appreciate the needs and circumstances of inmates being recruited for studies
- OHRP needs to provide guidance that enumerates the possible criteria and the levels of information needed for a prisoner representative. An appropriate prisoner representative would:
    - understand and appreciate the needs of inmates;
    - understand the correctional health and mental health delivery systems;
    - have an affinity for the incarcerated populations;
    - be an effective voice and not a bow to tokenism;

- function as a part of IRB at all times, not simply when prison issues are discussed, so that the representative gains credibility and finds an effective voice for communication within the IRB;
- understand the potential for coercion in prison settings; and
- know the configuration of the prison settings, populations and administrations.

OHRP needs to make clear, in any guidance and in public statements and presentations, that investigators, and not only IRBs, are responsible for evaluating the ethical issues in prison-based research and that investigators must communicate problems and propose solutions to the IRB to protect subjects' interests.

VI. Prisoner Representative on IRBs in Multi-Site Studies

Under current Subpart C regulations, although at least one member of an IRB reviewing a protocol must be a prisoner or a "prisoner representative with appropriate background and experience," in protocols subject to review by more than one IRB (e.g., multi-site studies), "only one Board need satisfy this requirement." Subpart C, Section 46.304(b). The Subcommittee feels strongly that it is insufficient and indefensible under the protective theories and spirit of Subpart C to allow a multi-site study involving incarcerated persons to proceed in correctional settings based on the approval of only one site's IRB, when that one site has a prisoner representative among its membership. The Subcommittee feels that each IRB overseeing such a study should include a prisoner representative, and that OHRP guidance should reflect this.

The Subcommittee also regards this "one IRB" requirement as wholly inadequate under Subpart A's protections of "vulnerable populations" to protect prisoners in one protocol who may be held in widely dispersed locations, and widely varied circumstances, and whose circumstances of participation may be very dissimilar. For example, having one prisoner representative from a prison system with a good health care system would seem insufficient by itself to allow approval of a study to move forward when the study also involves recruitment and participation of prisoners in state systems whose health care is clearly inadequate.

The Subcommittee therefore recommends that OHRP Guidance should state that even though, formally under Subpart C, one IRB with one prisoner representative would suffice for multi-site study review, the IRB of appropriate jurisdiction is responsible for determining the specific conditions in the local prison or jail that are pertinent to subject protection before approving the protocol for the local site.

In the case of central IRB review of a multi-site protocol, this would mean that the central IRB should consider the circumstances of each site, for example by requiring some report from researchers as to the conditions in the varied sites of a study. Only in this way can the IRB consider, under Subpart C and/or

Subpart A's protections of "vulnerable populations," the actual circumstances of prospective subjects. Otherwise, it seems to the Subcommittee impossible to have any assurance that consent and participation of subjects in each site are truly voluntary, or have even been gained in a private setting.

VI. Definition of "Minimal Risk" under Subpart C

After reviewing the Subpart C definition of "minimal risk" and comparing it to the Subpart A definition, the Subcommittee agreed upon the following:

1. The definitions of minimal risk are different in Subpart A and Subpart C in order to draw attention to the fact that there are differences in freedom of choice, in services available, and in risks faced, as compared between those in and outside of correctional custody.
2. The meaning of the difference is that prisoners, relative to non-prisoners, are unduly vulnerable to research risks that non-prisoners might find entirely acceptable. The definition of "minimal risk" in Subpart A is different from that in Subpart C because prisons are places of great psychological, physical, emotional and economic risk. The interpretation of this difference should be similar to the special interpretation of Subpart D for chronically ill children– additional risks on top of those already present are not justified.
3. IRBs should be given some standards by means of which to identify these differences.
4. Standards for the IRBs in this area, due to risk of abuse of incarcerated persons, should focus on justice and respect for persons and not on beneficence.
5. IRBs should focus on the special risks that prison life presents.
6. When IRBs contemplate the risk-benefit ratio of research they should begin with general considerations under Subpart A and then add the considerations that are highlighted under Subpart C. The definition of minimal risk should not ever work to lessen the protections for prisoners but rather to heighten them— leading IRBs and researchers to protect prisoners "as if" they were not incarcerated persons.

The Subcommittee recommends the following:

The existence of greater situational risk for prisoners does not justify a greater tolerance for research risk in the deliberations and judgments of the IRB, and risk standards for prisoners should have reference to healthy persons in safe environments, and should not reference healthy persons in a prison or correctional environment.

Using examples, new OHRP guidance should explain how minimal risk might be viewed for different protocols. OHRP guidance should result in this definition's working to heighten, not undermine, protections for prisoner-subjects.

VII. Expedited Review

The Subcommittee supports current OHRP guidance, which prefers review of prison research by a full convened IRB. Expedited review of protocols that fall under Subpart C would not necessarily include the input of the prisoner representative, thus frustrating the purpose of having such a representative in the first place. ***The Subcommittee recommends that in cases in which expedited review is used for Subpart C protocols, it would be preferred that a prisoner representative would be one of the reviewers.***

VIII. Control Group vs. Placebo

Subpart C regulations contain special provisions for prisoners in research who may be members of **"**control groups which may not benefit from the research." In current OHRP guidance, if one arm of a protocol conducted in prisoners provides "standard of care," that arm is considered to fall under Section 46.306(a)(2)(iv), into the category of "control groups which may not benefit from the research." The present OHRP interpretation is that the standard of care arm does not provide a "benefit" of research, rather it is a "condition" of research and therefore, such design is subject to special Secretarial review. (A control arm is a standard design concept in protocol construction as it is a bulwark against bias in the data.) At present OHRP and special Secretarial review are thus required when there is any research design in correctional settings that has a "control group," even if that control group receives the prevailing standard of care. This interpretation of the definition of "control group" has had the effect of delaying or deterring research that is *decidedly not* the category of research intended to be restricted by Subpart C.

The Subcommittee understands that the position of OHRP that *any* "control arm" (not just a control arm that provides a placebo, *i.e*., no treatment), requires Secretarial review was a position first taken approximately four years ago. This position is a departure from previous OPRR positions that only placebo, with no active substance and thus deviating from standard of care, required Secretarial review.

In interpreting the language of the regulations three considerations must be at the forefront:

1. An historical point: the research that was designed to be prohibited (abusive medical research, with control groups given no treatment, or such "guinea pig" studies as those involving Retin A in the Pennsylvania prison system) is not the research presently prohibited by current OHRP interpretation of the "control group" criterion (which imposes a higher level of review and thus delay, even when control groups receive standard of care).

2. An epidemiological point: a control group *does benefit* from well-designed research because that research is adding to general knowledge about this condition that afflicts the group.
3. A practical, clinical point: in a clinical trial, as data points are monitored more rigorously than in general medical care, the researcher is often seeking and achieving a tighter monitoring of the patient's condition, even for those patients in the control group, which provides an additional benefit to those patients enrolled in the "standard of care" arm of a clinical trial.

The Subcommittee agreed that the current OHRP interpretation provides no room for an analysis based on "clinical equipoise," is thus at odds with all prevailing research ethics analysis, and should be changed. As there has not been any official OHRP guidance on this point, it may be possible to change practice without engaging in lengthy administrative rule making. According to the Subcommittee's view, if standard of care is provided and if both arms of a protocol must provide at least that standard of care, then the inmate is benefiting from both arms of the protocol, and Secretarial review should not be triggered.

The Subcommittee, after long discussion of this current OHRP interpretation, reached a consensus that the previous OPRR interpretation is ethical and defensible, and fully consistent with the text of Subpart C. The Subcommittee strongly recommends that OHRP revert to its previous interpretation of this provision of Subpart C.

The Subcommittee also recommends as follows:

OHRP guidance should be changed to be more in accord with standard views of the research community, under which standard of care would be considered to be an arm of a trial providing benefit.

In addition, guidance should specify that a protocol with a placebo arm in a study for which there is standard treatment for the condition, would be considered an arm not "benefit[ting] from the research," thus requiring an expert panel consultation.

IX. Additional Subcommittee Views on Standard of Care and the Ethical Conduct of Research among Prisoners

There has been general Subcommittee agreement that the prison or jail health care service must provide the standard of care in treatment to all inmates, or else research protocols on those issues cannot ethically be performed at a correctional facility. It has also been agreed that most of the discussion on this issue perforce relates to medical research—especially clinical trials – and not to socio-behavioral research. This is buttressed by the observation that it is only medical research that is likely to be of sufficient risk to trigger this analysis.

Indeed, a standard ethical review of research would say that, when given the opportunity, the research should be done with the least vulnerable, and not the most vulnerable, population. This would exclude prisons in most research from qualifying as an acceptable setting, and this exclusion is ethically supportable. There is a need to distinguish clinical trials —which treatment is better – from operational research—how can we give treatment more effectively in these prison settings. The former need standard of care services in place as a backdrop for the research; the latter may not have an equal need for standard of care services in place, as the issue being investigated might be how best to get such standard of care services into place.

Whether or not the institution is providing standard of care would be a judgment that the researchers, who are experts in the field, must ascertain as an ethical matter before proposing their research. This might require a random review of records, procedures and protocols. If standard of care is not provided, then a research protocol predictably would exert a coercive influence on inmates, who would judge that only by joining the protocol would they get appropriate care. That would not be ethically permissible. Further, it is argued: if good clinical treatment has not been provided and will not be provide to a control group, then how can clinical research be valid in such a setting?

This Subcommittee, after extensive discussion with SACHRP on these issues at the January 2005 meeting, would recommend that these issues be considered by the Institute of Medicine Committee that will be reviewing current federal policies relating to research among prisoners.

X. Interpretation of "Follow-up" Requirements

Under Section 46.305(a)(7), one of the required seven findings to be made by an IRB is: "where the [IRB] finds that there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact."

The issue that has perplexed many IRBs and investigators as they have tried to apply this criterion has been whether "follow-up examination and care" refers to follow-up of an incarcerated person who is released from correctional custody during a study, and/or to follow-up care of subjects who remain incarcerated after a study has ended. *The Subcommittee consensus was that "follow-up examination and care" should be interpreted to include any examination or care that is necessary after the end of a study or after a subject can no longer participate in a study due to release*. The primary rationale for the Subcommittee's belief is its determination that the safety and welfare of all subjects would require consideration of both eventualities: release from custody during the study, or the ending of a study for persons who remain incarcerated.

After extensive discussion with SACHRP at SACHRP's January 2005 meeting on this issue, the Subcommittee makes no specific recommendation, but commends the need for clarification of this issue to the Institute of Medicine, in its full reconsideration of the standards of Subpart C.

XI. Future Work by the Institute of Medicine

The charge of this Subcommittee has been to examine the present federal regulatory structure and assess, in the short term, what clarifications would help researchers and IRBs to protect the interests and rights of prisoners as subjects of research. Over the long term, strategy needs to focus on rewriting the Subpart C regulations. The Subcommittee therefore endorsed OHRP's request to IOM that it form a committee to address the present framework for reviewing research with prisoners, and to consider the relevant principles and circumstances governing research with prisoners. Of particular concern to the Subcommittee – and a topic that the Subcommittee would specifically commend to the attention of the IOM – is the current narrow jurisdiction of Subpart C, which now covers only research funded by HHS, and with some procedural exceptions, research overseen by IRBs that have voluntarily agreed to apply Subpart C to all prisoner research, regardless of source of funding. The Subcommittee would suggest that an IOM committee examine the possibility and wisdom of larger aegis for enhanced protection for prisoners in research —state, federal, agency compacts or actual pre-emptive authority of new regulations.

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