Secretary's Advisory Committee on Human Research Protections

Meeting
March 29-30, 2004
Alexandria, VA

Summary Minutes

TUESDAY, MARCH 30

Welcome and Opening Remarks
Ernest Prentice, Ph.D.
Dr. Prentice welcomed participants to the second day of the March, 2004 SACRHP meeting and commended the Committee for working so efficiently.

Litigation in Clinical Research: Problems and Solutions *(E. Haavi Morreim, Ph.D., Professor of Bioethics, University of Tennessee))*
Dr. Morreim discussed developments in case law and legislation as they relate to current clinical research issues, especially the challenges faced by IRBs.

Litigation Trends
Dr. Morreim explained that it is difficult to gather accurate trend information because many cases are settled out of court. She referred SACHRP members to her previously sent article for additional information. (Morreim, E.H.; Medical research litigation and malpractice tort doctrine: courts on a learning curve, *Houston Journal of Health Law and Policy* 2003; 4(1): 1-92.)

Potential Sequelae
Dr. Morreim observed that IRBs are very concerned about whether their decisions could result in litigation. She identified nine potential sequelae in this litigious atmosphere:

1. Difficulties finding people to serve on IRBs
2. Increased length and complexity of consent forms
3. Excessive emphasis on documentation
4. Full review of protocols that could be expedited
5. Multiple IRBs where one central Board would be acceptable
6. Unwieldy levels of adverse event (AE) reporting
7. Reluctance of prospective investigators to undertake research
8. Increased inclination of IRBs to disapprove studies
9. Increased cost for sponsors, including government, via higher indirect costs to cover liability insurance

Insurance Challenges and Potential Responses

In the current environment, entities involved in research efforts have difficulties obtaining adequate insurance. Only two insurers remain in the market and the policies they offer often have serious gaps in research coverage. Current challenges include increasing:

- Sponsor requirements for cross-indemnification
- Premiums and deductibles (although it is difficult to track actual increases)
- Refusals by insurance carriers to cover for pediatric and obstetrical trials

Other problems included the following:

- Insurers' knowledge of research structure and levels of risk usually is limited
- Some states are mandating higher levels of coverage
- Growing insurance costs are not built into grants' indirect cost allowances
- Some small sponsors have insufficient funds to cover insurance
- Some investigators are protecting their personal assets separately

A better economy will help resolve many of these problems. Other solutions involve:

- Working with brokers to--
  - Educate insurers about various research players' diverse roles and varying risk levels involved in conducting studies
  - Negotiate reduced rates
- Using market-based techniques, such as--
  - Group purchasing consortia
  - Special riders to cover research
  - Group self-insurance (although there are significant obstacles to this)

Settling without Going to Litigation

Settling without litigating often is very appealing to research institutions because they avoid the related costs and uncertainties as well as possible bad publicity and requirements to release sensitive information. In addition, some insurance policies mandate settlement with or without the consent of the insured. However, in the absence of judicial evaluation, plaintiffs may make significant claims about various parties' responsibilities that may linger as "quasi-standards."

Alternatives to Settling or Litigation: Arbitration

IRBs have not been able to rebut many unrealistic claims regarding their "responsibilities" because of institutional pressure to go to settlement. However, arbitration may provide an alternative to settlement or litigation that would enable IRBs to rebut these claims.

The Federal government has evinced increasing interest in arbitration, and the States are following suit. Arbitration is simpler and quicker than going to court and involves relaxed rules of discovery and fewer administrative expenses. In addition, arbitration can provide limited compensation and can be conclusive if specified as binding. The drawbacks of arbitration fall mainly and the plaintiff and include limited: discovery, judicial review, procedural protections, and time to file.

Recent decisions demonstrate that judges' are moving to consider arbitration as:

- Contractual
- A different forum for seeking enforcement of rights, rather than a waiver of rights
- A procedure placing the burden on the party contesting the arbitration clause.

In crafting arbitration agreements, research institutions must take special precautions to ensure that the results are enforceable. In the research context, these precautions include:

- Providing a take-home copy of the consent form, including the arbitration agreement
- Carefully drafting the agreement so that the only authorized signatures are those of the research subject or his or her legally authorized representative.
- Including few or no costs for research subjects.
- Providing a revocation period (ideally 30 days)

In addition, arbitration procedures must be within the research subject's reasonable expectations and participation must be fully voluntary (i.e., not a prerequisite for entering the study).

Alternatives to Settling or Litigation: Federal Immunity for IRBs. Providing IRBs with the qualified (presumed, but not automatically assumed) immunity could protect the Boards from unrealistic lawsuits, although legislation probably would be required before this remedy could be made readily available. Qualified immunity could:

- Protect IRB members as thought they were government employees, based on the rationale that IRBs are Federally mandated and involve Federally mandated and specified activities.
- Reduce the number of suits, the costs per suit, and the costs of insurance.
- Enhance willingness to serve on IRBs.

Dr. Morreim discussed three models of qualified immunity that could be adapted for IRBs. They are, respectively, based on:

- The Health Care Quality Improvement Act (HCQIA)
- The Federal Torts Claim Act (FTCA)
- § 1983/Bivens

HCQIA. This law was enacted to protect peer review in health care institutions. It stipulates that reviewers will not be liable in damages if a "professional review action" meets certain standards of due process and fairness,. (This immunity applies to money damages, not lawsuits.) Decisions are made by judges, not juries, and the burden of proof falls on the plaintiffs. In making judgments, the standard applied is reasonableness, not good faith. Case law has upheld HCQIA.

Dr. Morreim offered a draft version of HCQIA adapted for use by IRBs. For purposes of the protections set forth in this law, she proposed that an IRB action must be taken:

1. "In the reasonable belief that the action [in question] was in furtherance of protecting human research subjects.
2. After a reasonable effort to obtain information that might be needed to review the adequacy of the protocol's human research protections.

3. After reasonable deliberation concerning the adequacy of the protocols human research protections.
4. In the reasonable belief that the IRB's final decisions were warranted by the facts."

FTCA. This Act waives sovereign (absolute) immunity and allows the Federal government, rather than its employees, to respond to tort suits in certain situations. Judges, not juries, decide these cases and no punitive damages may be awarded. Under this Act, IRBs would have greater freedom to carry out their mission, their insurance costs would decrease, and members' personal liability would be eliminated.

In her rationale for including IRBs under the Act, Dr. Morreim noted that:

- FTCA applies to Federally mandated, specified, supervised activities undertaken by entities created to serve the public interest.
- The law protects these entities from suits based on discretionary decisions involving social, economic, and political policy.

In addition, the Act already has been used to protect migrant health centers from the costs of comprehensive malpractice insurance.

§ 1983/Bivens. These decisions protect Constitutional rights yet also protect public officials from suits based on errors in judgment. Federal employees have qualified immunity and the plaintiff must demonstrate that the government representative: (1) violated a Constitutional right that was clearly established and (2) that "a reasonable person would have known that this conduct violated a Constitutional right." Judges, not juries, decide these cases and no punitive damages may be awarded.

Dr. Morreim presented her tentative conclusions about the implications of these decisions for IRBs. She noted that IRBs:

- Like the other covered entities, exist by government mandate to serve public policy functions.
- Would be granted qualified immunity as long as they act within the scope of Federally mandated activities.
- Would be liable only if their conduct violates an established Constitutional right knowable to a reasonable person.

Recommendations

Dr. Morreim recommended that IRBs take action to obtain qualified immunity via legislation. She identified six key features to be included in the immunity bill:

1. Reasonableness of conduct secures immunity
2. Judges, not juries, determine immunity
3. The burden of evidence is placed on the plaintiff
4. Immunity covers--
    - Monetary damages (minimal requirement)
    - Suits (ideal)
5. No punitive damages may be assigned
6. If the defendant prevails, the plaintiff pays all litigation costs

In addition, Dr. Morreim made the following overall administrative recommendations:

- Mechanisms should be developed to track litigation; these should be based on filed complaints and outcomes.
- IRBs' duties should be more precisely described, especially for the ongoing monitoring of informed consent and research conduct.
- Creative market responses should be developed to address emerging insurance needs.

Discussion of Dr. Morreim's Presentation

Dr. Prentice thanked Dr. Morreim for her concision and clarity and for presenting SACRP with new approaches to a serious problem. He added information about a recent case that could set a "quasi-standard." In the case of *Richard Cuss v. Sherman Hospital,* the Illinois appellate court ruled that the IRB had to be certain that participants signed and used the correct consent forms. Ultimately, the case was settled out of court.

Dr. Prentice asked two questions:

1. Given that a subject is likely to receive compensation by pursuing a suit, why would he or she voluntarily agree to arbitration?
2. Does arbitration provide protection for IRBs?

Dr. Morreim explained that many court suits are denied or involve long amounts of time and sizeable awards to attorneys. It is not clear how long plaintiffs must wait to collect funds from judgments or how much money they receive. The advantages of arbitration are that plaintiffs are more likely to collect these smaller claims and to do so more rapidly. Nonetheless, because of the negatives associated with arbitration, Dr. Morreim recommended moving to this approach only if qualified immunity cannot be achieved. She added that, in her reading of the law, there are various ways to write IRB protections into arbitration contracts. Drs. Prentice and Morreim agreed that plaintiffs would be less likely to include IRBs in any kind of suit if an arbitration contract were in place.

Dr. Hauser asked Dr. Morreim to recommend mechanisms for tracking litigation. Dr. Morreim suggested creating a central, informal registry of information about IRBs and others involved in public complaints concerning research. She was not familiar with specific mechanisms for putting registries in place.

Dr. Hauser also asked how immunity would be extended to IRBs and what the Boards would need to do to qualify for immunity. Dr. Morreim responded that extending immunity via the HCQIA or FTCA model would require Congressional legislation. To qualify for immunity, the IRBs would have to comply with criteria specified in the legislation. (Those included in the HCQIA were more general than those specified by the FTCA.) Moving forward under the § 1983/Bivens model would require judicial decisions, ideally on the Supreme Court level.

Mr. Barnes observed that DHHS could capture much of the litigation data using the National Practitioner Data Bank (NPDB) created by the HCQIA. HHS has the authority to expand NPDB so that research-related settlements and judgments are recorded. Dr.

Morreim observed that the expanded databank would need to track filings as well as outcomes.

Although not his viewpoint, Mr. Barnes reported that plaintiffs' attorney Allan Millstein considers IRBs lazy and negligent. Mr. Millstein views the tort system as a good way to punish IRBs and ultimately reform their behavior. Dr. Morreim replied that the tort system does not work the way it should. The immunity system she propounds is a better remedy for addressing IRB problems. Nonetheless, some of the suits against IRBs have been useful wake-up calls to the field.

Dr. Khin-Maung-Gyi asked whether requiring subjects to review arbitration materials as well as other required documents could be viewed as placing too heavy a burden on participants. Dr. Morreim agreed that this requirement could be considered a negative aspect of arbitration. However, having an arbitration process in place probably would result in IRB performance that was more flexible and perhaps more beneficial to subjects. In addition, as she mentioned earlier, arbitration benefits subjects in other ways.

Dr. Fisher made several comments. She suggested that collecting data would be difficult because institutions are reluctant to make this information public, and she raised concerns about:

- Using the analogy equating IRBs and peer review boards
- Considering an IRB to be an arm of the government
- Putting undue burdens on patients, as mentioned by Dr. Khin-Maung-Gyi

In addition, Dr. Fisher asked:

- How best to operationalize elements that must be ensured by IRBs.
- For further discussion of protections of IRBs as entities and protections of individual IRB members and PIs.
- For clarification about how Dr. Morreim's recommendations would be applied when research subjects use their own health insurance to pay for participation
- Whether IRBs and PIs would provide patients with appropriate information if they viewed subjects as potential adversaries in arbitration cases.
- Whether granting immunity would weaken the "wall" separating IRBs and their institutions, resulting in weaker subject protections.

Dr. Morreim's responses included the following points:

- Operationalizing voluntary reporting will be a challenge, but the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) provides a model that could be built upon and improved.
- When institutions are served with process papers, this is part of the public record and should be relatively easy to capture in the databank.
- Adversarial relations between IRBs and subjects may develop, but this is less likely to occur when arbitration, rather than litigation, is used to resolve disagreements.
- The analogy between peer review boards and IRBs is based on the fact that both entities engage in a particular process focused on safeguarding individuals and the health care system. This Federally mandated public service could be significantly

misdirected when individual members, or the entities themselves, are at risk for being named in lawsuits without merit.
- The roles of the IRB, both as a possible arm of the Federal government and as a guarantor of specific subject protections, needs further clarification.
- All of her recommended protections pertain to protecting IRBs, not sponsors or PIs.
- Whether IRB protections are considered for the entity as a whole or its individual members, the absence of these protections has the same results--greater difficulty in appropriately constituting IRBs.

Before the session concluded, the following additional points were made:
- Ms. Kornetsky agreed with the statement made by Drs. Fisher and Khin-Maung-Gyi about possibly putting an unduly large burden on subjects by asking them to review arbitration materials as well as the other documents governing research studies.
- Dr. Morreim said an appropriate way for the Federal government to educate insurers would be to work with insurance brokers and let them pass along information.

SACHRP members thanked Dr. Morreim for her presentation.

Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Panel

The Privacy Rule and Research (Susan McAndrew, Senior Policy Specialist/HIPAA, Office for Civil Rights, Office the Secretary, DHHS)

Ms. McAndrew provided an overview of the Privacy Rule in her PowerPoint presentation, *The Privacy Rule and Research*.

The Rule was issued by HHS to meet HIPAA implementation requirements. Staff at the Office for Civil Rights (OCR) provide technical assistance regarding the Rule and investigate complaints. The Rule provides two types of protection:
1. It provides individuals with access to their medical information and enables each individual to make corrections and request details about how the information is used.
2. It protects the privacy of identifiable health information by limiting how a covered entity (CE) can use and disclose that information.

The research provisions of the Rule enable CEs to use and disclose protected health information (PHI) with individual authorization or, under limited circumstances, without individual authorization. The Rule's authority extends beyond those agencies regulated under the Common Rule or by the FDA; it applies to: (1) any research that includes treatment of research participants (e.g., clinical trials) and (2) records research using existing PHI (e.g., databases and repositories). However, the Rule does not override the Common Rule or FDA's human subject protection regulations.

Common Rule v. Privacy Rule. The Privacy Rule authorization process has been streamlined, and researchers should be able to mesh both sets of requirements into a single document when they judge this to be appropriate. As part of the streamlined process, Privacy Rule research authorizations:

- No longer need expiration dates.
- Have been modified to more closely resemble the Common Rule provisions for waiving the informed consent requirement and for enabling activities not requiring IRB approval to go forward.

Use and Disclosure of PHI for Research without Individual Authorization. OCR has developed four options to govern use and disclosure without individual authorization.

- ***Option One:*** Documentation is obtained demonstrating that an IRB or Privacy Board has approved an alteration to, or a waiver of, authorization based on the following three waiver criteria--
  1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals.
  2. The research could not practicably be conducted without the alteration or waiver.
  3. The research could not practicably be conducted without access to and use of the PHI.
- ***Option Two:*** Representation is obtained demonstrating that the use or disclosure is necessary to prepare a research protocol or for similar purposes preparatory to research. In these cases, no PHI can be removed from the CE.
- ***Option Three:*** Representation is obtained demonstrating that the use or disclosure is solely for research on decedents' PHI.
- ***Option Four:*** The research only uses or discloses a limited data set of "indirect identifiers" (e.g., zip code, dates of service, age, death). A data use agreement must be signed as part of this option.

Accounting for Research Disclosures. Upon request, the CE must provide the individual with an accounting for research disclosures made without his or her authorization (except for research conducted under Option Four). In 2002, this requirement was relaxed for CEs conducting a great deal of research or large research studies (50 or more records).

CE and Researcher Relationship. The researcher and the CE are two separate legal bodies. The Privacy Rule can apply to the entire entity or a hybrid status may be developed in which the treatment and research components are separated and the latter becomes a third entity.

Resources and Future Plans. Ms. McAndrew directed SACHRP to the OCR and NIH Websites, respectively, for additional information:

- http://www.hhs.gov/ocr/hipaa/
- http://privacyruleandresearch.nih.gov/

She also noted that OCR is working with NIH on issues related to international research and is tackling the recommendations developed by the National Committee on Vital and Health Statistics (NCVHS) at their November meeting, focusing particularly on clarifying Privacy Rule provisions for stand-alone authorization and patient recruitment.

Association of American Medical Colleges (AAMC) Project to Document the Effects of HIPAA on Research (Susan Ehringhaus, J.D., AAMC Associate General Counsel)

Susan Ehringhaus discussed the purposes, conduct, and results of the AAMC project.

The 2003 AAMC HIPAA Survey was undertaken to document the effects of HIPAA on biomedical and health sciences research and to probe broadly defined HIPAA-related costs. A database of case reports was created to identify instances of research being delayed, hindered, abandoned, or foregone due to HIPAA as well as research that benefited as a result of the Act.

Survey steering committee members were drawn from a range of professional health and medical associations. AAMC member institutions, working through designated representatives, collaborated in the project. The following AAMC principles guided the conduct of the survey:

- Research must be conducted ethically and with scientific integrity
- Protection of human subjects is of paramount importance.
- Standards should maximize the utility of de-identified information.
- Standards must clarify the duty of researchers to safeguard subjects' privacy.
- Protection of medical information from harmful use is crucial.

The majority of survey respondents were investigators (62%), followed by study coordinators/managers (18%) and research administrators (9%). Other respondents targeted by the survey were: IRB personnel, officials concerned with privacy regulations, and medical school deans.

The survey found that:

- Seventy-two percent of clinical research was affected by HIPAA.
- Patient recruitment and data access were the research functions most severely impacted by HIPAA.

The types of effects of HIPAA on research include the following:

- Confusion/distractions for potential subjects
- Recruitment impaired or prevented
- Access to research participation opportunities diminished
- Informed consent burdened
- Subject bias introduced
- Ability to do research hindered/shifts in research directions necessitated
- Difficulties in collaborations
- Burdens of researchers/staff; additional bureaucracy in the research process
- Impact on research quality
- Increase/shift in research costs
- Conflicting interpretations of HIPAA requirements

Ms. Ehringhaus cautioned SACHRP that the interpretation of the responses is limited by the relatively small size of the data set. It also is limited because the questions were asked in the earliest phase of HIPAA compliance and the initial interpretations of the regulations tended to be very conservative. Nonetheless, AAMC's findings confirmed the results of the National Cancer Advisory Board (NCAB) survey of National Cancer

Institute (NCI) Cancer Centers, Cooperative Groups, and Specialized Programs of Research Excellence (SPOREs). Based on both surveys, AAMC developed the following recommendations to improve HIPAA implementation:

Eliminate the accounting of disclosures for research (consistent with NCAB results). For studies involving fewer than 50 subjects, the accounting of disclosures represent a large regulatory burden and ultimately will reduce the research base for epidemiological and health services studies. Research involving 50 or more subjects is generally carried out at major research entities conducting multiple protocols. The accounting for disclosures requirement puts an unreasonable burden on these institutions for assisting individuals in retrieving information and is a negative incentive for institutions to participate in research involving many subjects.

- ***Modify the requirements for research authorizations and waivers*** (consistent with NCAB results). When informed consent and IRB approval exists and other specific criteria are met, the requirement for authorizations or waivers should be eliminated.
- ***Relax the de-identification standard*** (consistent with NCAB results). A more realistic standard is needed; this could incorporate unique identifiers not shared with researchers.
- ***Shift from an organizational to a functional focus*** (not addressed in NCAB survey). The current standards for CE, HE or ACE status are too exacting, do not reflect current organizational integration, and create barriers to interdisciplinary and inter-institutional research.

Additional information about the survey can be found on the AAMC Website, http://services.aamc.org/easurvey/survey/login.cfm. The Website provides information on the results categorized by research function affected, nature of the problem, attempted resolution, and role of the respondent.

The HIPAA Privacy Rule and Research: Recommendations of NCVHS (Mark A. Rothstein, J.D., Chair, NCVHS Subcommittee on Privacy and Confidentiality)

Mark Rothstein discussed the NCVHS recommendations and the resulting letter to Secretary Thompson--*Recommendation on the Effect of the Privacy Rule, March 4, 2004.*

NCVHS is a statutory Federal advisory committee providing guidance to Congress and the DHHS Secretary. The Committee comprises workgroups and subcommittees on specific topics. On November 19-20, 2003, the Privacy and Confidentiality Subcommittee held hearings to gather expert testimony on the impact of the HIPAA Privacy Rule on research. Five conclusions were developed:

1. Researchers believe that the Privacy Rule has detrimental effects on research. However, this may reflect: (a) researchers' general dissatisfaction with regulations and (b) misunderstandings of HIPAA by the possessors of health data.
2. There is wide support for aligning the Privacy and Common Rules.
3. Researchers and IRB members are confused about the Privacy Rule. However, this appears to be lessening over time.
4. There are inconsistencies between the Privacy and Common Rules.
5. Clarification and additional educational activities are needed.

Inconsistencies between the Privacy Rule and the Common Rule. Mr. Rothstein noted that the inconsistencies result in gaps in protection, create burdens on researchers, and contribute to confusion about research procedures. Specific problems that have arisen include the following:

- Under the "preparatory to research" provision, researchers and their business associates may contact patients and ask them to authorize the use of their PHI without prior submission to an IRB for approval or waiver. This violates the IRB's primary directive: to review research before recruitment starts.
- The Privacy Rule permits the use of a combined informed consent/authorization document, but many institutions prefer to use separate forms.
- Because the Privacy Rule does not require IRB approval of stand-alone authorizations, some IRBs believe they are prevented from reviewing these documents.
- Under the Common Rule, IRBs may allow research subjects to provide informed consent for future, unspecified research. However, under the Privacy Rule, authorization generally must be protocol-specific and, therefore, a waiver or alteration from an IRB or Privacy Board would be needed before PHI could be disclosed from a repository. This creates unnecessary burdens on researchers.

Other Areas of Concern Noted by NCVHS. Mr. Rothstein noted that additional issues were identified at the November hearings. Members expressed concerns about:

- Consistent protection for indirect participants in research.
- Special issues that arise when multi-site trials are conducted.
- The refusal of smaller institutions to participate in research.
- The lack of protection for anonymous information (e.g, genetic samples).

Recommendations to the DHHS Secretary. On March 5, 2004, NCVHS sent a letter to Secretary Thompson recommending that HHS clarify the intent and provisions of the Privacy Rule and make further efforts to harmonize the Privacy and Common Rules.

Presentation to SACHRP *(Joanne E. Pollack, J.D., Vice President and General Counsel at Johns Hopkins Health System, Inc.)*

Joanne Pollak discussed the practical impact of the Privacy Rule on an academic research institution, focusing on: (1) medical archives in CEs, (2) future unspecified research, and (3) the harmonization of HIPAA and Common Rule authorizations.

Medical Archives. These are documents held by a medical institution; they include the records of patients and physicians, some of which may be very old. Under the Privacy Rule, two critical issues have arisen: access and publication.

- ***Access:*** Historians and other researchers needing access to documents often can be accommodated by expanding the definition of "conducting research." However, other situations must be handled on a case-by-case basis. Archivists at CEs increasingly spend their time reviewing information requests and crafting responses that meet Privacy Rule requirements. At some CEs additional problems have arisen

because prominent medical professionals are reluctant to donate materials once they learn that the future use of these documents will be circumscribed.

- ***Publication:*** Dissertations, although usually published in a limited way, meet the Privacy Rule definition of "publication." Many photographs included with published materials also meet the definition. As a result, document and photograph identifiers must be eliminated, which can be very time-consuming.

To resolve these problems, Ms. Pollak suggested: (1) developing designated data sets to which HIPAA would not apply and (2) asking the institutional privacy board to determine what types of materials might appropriately be released. In addition, donors might be asked to provide written statements releasing materials for general use after a certain number of years.

Future Unspecified Research. Under the Common Rule, people may donate tumors and other tissue to medical registries for future research studies and no further informed consents are required. However, under the Privacy Rule, researchers must get IRB waivers or donor authorizations for every study using the tissue. This creates a serious burden for researchers and is confusing to donors. The solution is for HIPAA and the Common Rule to be harmonized in this area. IRBs should be allowed to determine the adequacy of the first consent form and whether other protections are needed. If current practices continue, individuals will become increasingly reluctant to donate tissue, DNA, and data to CE registries and the new unregulated databank industry will flourish.

Harmonization of HIPAA and Common Rule authorizations. Ms. Pollak made the following points:

- The Privacy Rule has a broad purview because Congress wanted to: (1) provide privacy protections for individuals participating in non-HHS research and (2) address what they perceived as IRBs' lack of attention to subject privacy.
- At present, institutions can use a single form to address related Privacy and Common Rule concerns. However, drafting this form for specific protocols can be extremely time-consuming; as a result, many researchers prefer to use two forms.
- The lack of true harmonization creates confusion among researchers and subjects.
- To resolve harmonization issues, stronger privacy protections should be included in the Common Rule, which should then be the standard for studies conducted under the authority of HHS or FDA. Other studies should be covered by the Privacy Rule, and a simplified authorization form should be provided to subjects.

SACHRP Discussion of the HIPAA Privacy Rule

Dr. Prentice thanked the panelists for their informative and thought-provoking presentations. He noted that researchers at the University of Nebraska Medical Center have not had many problems with the Privacy Rule. The Center uses a form combining Common Rule consent and HIPAA authorization; the only research sponsors that have trouble with this are pharmaceutical companies. These sponsors are not CEs and do not have to comply with the Privacy Rule; however, the University Medical Center is a CE and must follow the Rule. The resulting conflicts have led to protracted legal negotiations,

especially concerning contract language. He asked the panelists if they were familiar with this problem.

In response, Ms. Pollak said that Hopkins has had similar problems and has successfully negotiated for the use of limited data sets or de-identified information or the inclusion of additional information in the authorization. Mr. Rothstein added that a uniform resolution for this type of problem is needed. Dr Prentice agreed.

Dr. Hauser asked whether the HIPAA rules had adversely affected researchers' ability to conduct safe clinical studies. Ms. Ehringhaus responded that, according to the AAMC survey, the need to use de-identified data increases the possibility for errors in data interpretation. In addition, survey respondents noted that retrospective research using treatment records was made more difficult by HIPAA.

Ms Kornetsky asked Ms. McAndrew whether many HIPAA-related complaints involved research studies. Ms. McAndrew explained that "research study" is not among the categories used to analyze complaints. She speculated that research studies accounted for few complaints; however, some of the categories, such as "impermissible use of information" could include research studies. Ms. McAndrew added that, during the Rule comment periods, a great deal of concern was expressed about protecting personal data in research studies.

Mr. Adams asked Ms. McAndrew about progress being made in harmonizing the Privacy and Common Rules. Ms. McAndrew replied that conversations are underway to facilitate harmonization.

Dr. Khin-Maung-Gyi asked how the Common Rule might be strengthened so that it might be used instead of the Privacy Rule in studies conducted under HHS or FDA authority. Ms. Pollak suggested that OHRP and FDA might provide guidance that would require researchers to disclose the types of information they would be collecting and how it would be used. Alternatively, the Privacy Rule might be amended to ensure that specific items related to subject privacy are included in the informed consent documents. The list of required privacy protection items would be shorter than the list currently required under the Privacy Rule. Ms. Ehringhaus reported that AAMC favors the latter solution.

Mr. Barnes outlined two scenarios and asked Ms. McAndrews specific questions about them.

1. Doctors are accustomed to including information about one, two, or three subjects in case studies they write for publication without having to obtain IRB approval. Given that these case studies are not considered research under the Common Rule, what is their status under the Privacy Rule? Must the individuals described in a case study provide authorization?
2. Johns Hopkins wrote a letter to OCR requesting permission to obtain authorizations from patients upon admission that would enable the CE to review their records, determine whether the individuals might be qualified for studies, and recruit them as appropriate. What is the OCR response to this letter?

Ms. McAndrew replied that:

- Regarding the first scenario, each individual's permission to publish would be needed if his or her identity could not be disguised.
- Concerning the letter from Johns Hopkins, a recent OCR clinical studies fact sheet discusses the development of lists of potential research subjects. In general, patients can be included in the lists if they have provided authorizations.

Mr. Barnes observed that the publication ruling could have a chilling effect on the dissemination of important scientific knowledge. Ms. Kornetsky added that case studies usually report rare occurrences and necessitate the use of unique identifiers. Therefore, OCR's position on publication means that HIPAA authorization would be required for publishing most case studies. Ms. McAndrew responded that individuals should have some say in how their personal information is used. Mr. Rothstein added that it is appropriate to obtain authorization prior to publishing information that might lead to the identification of an individual, especially by the press or general public.

International Activities Report

Dr. Polan presented *Office of Human Research Protections International Activities*, the report she drafted with fellow SACHRP member Nancy Jones and:

- David Borasky, Office of International Research Ethics, Family Health International
- Melody Lin, Ph.D., Deputy Director, OHRP
- Helen McGough, Director, Human Subjects Division, University of Washington.

Dr. Polan explained that the Report and presentation were meant to stimulate discussion and the possible appointment of a Subcommittee to further study international issues and draft formal recommendations. As part of the Report, the international study group developed three recommendations for SACHRP consideration:

1. HHS resources should be made available to support host country infrastructure development for appropriate initiation and monitoring of clinical studies. For example, such funds could be line items in grant applications to NIH and could be supported by additional funding through the NIH Fogarty International Center (Fogarty Program).
2. OHRP, with appropriate outside support and consultation, should develop and publish guidance for building IRB capacity in host countries.
3. Federal agencies should offer to match private funds from educational institutions and foundations that are used to build capacity in host countries for IRB development, information technology, and monitoring of clinical trials.

Dr. Polan also identified more complex issues for SACHRP to address. These included:

1. Clarifying OHRP determinations about regulatory equivalence and simplifying the Federal Wide Assurances (FWA) language.
2. Evaluating available training and developing specific courses for American PIs who will be conducting research overseas

3. Promoting collaborations among Federal regulators to harmonize ethics standards and provide a clear regulatory pathway to be followed in international research.
4. Systematically reviewing sources of funds for international research to: assess the magnitude of the research, clearly identify the challenges, and develop educational programs to address these challenges.

Discussion of the International Activities Report

Dr. Jones noted that international research is a growing field and suggested that funding agencies should be asked to justify their international research programs, with a focus on ethics issues. These are of particular concern because sponsors appear to be drawn overseas by the generally lower levels of regulatory requirements and costs. Other comments included the following:

- Mr. Adams asked whether the cost implications had been calculated for implementing the first three recommendations. Dr. Polan explained that the small group did not have the resources to make these estimations; however, a Subcommittee would be able to develop these estimates.
- The pharmaceutical industry should be included under the fourth "complex issues" bullet.

SACHRP members noted that a proactive approach to the issue was needed. As a first step, a timeline for the discussion of international issues should be developed.

Issues for Discussion by SACHRP: IRB Review of External Adverse Event Reports (AERs) *(Ernest Prentice, Ph.D.)*

Dr. Prentice described IRB problems with AERs and outlined a potential solution.

Problem: AER Overload

Eight factual statements describe the current problem:

1. IRBs are overloaded with external AERs from multi-center drug trials. (For example, Washington University in St. Louis School of Medicine receives 12,000 AERs annually)
2. Investigational New Drug (IND) safety reports do not contain adequate information.
3. IRBs are not constituted to act as Data Safety Monitoring Boards (DSMBs).
4. Fear of litigation is driving the system.
5. The problem continues to grow and consume already strained IRB resources.
6. Consumption of these IRB resources impacts the IRB's ability to engage in other important activities.
7. Some IRBs have over-interpreted the regulations. (For example: although the Common Rule does not specifically require all IRBs of record to review external AERs that occur in multi-center trials, many IRBs feel compelled to do this.)
8. OHRP and FDA expectations concerning AE review have not been clearly articulated in an official guidance document.

Proposed Solution

Based on his experience in the field and discussions with representatives from key organizations, Dr. Prentice proposed components of a possible solution:

- The sponsor and/or the DSMB should triage AERs and only require notification of all IRBs if:
  - The protocol requires modification OR
  - The consent form requires revision to disclose a new risk OR
  - A problem exists that affects the study.
- The sponsor should continue to notify PIs of all AEs that meet the IND reporting requirements in the Common Rule (i.e., AEs that are unexpected, serious, and associated.)
- The PI should be responsible for analyzing the AER and determining if local action is needed. If so, the AER and changes should be sent to the IRB.
- The PI's analysis and determination should be documented and subject to audit. (PIs should file these documents for IRB audit as needed to meet protocol monitoring requirements.)
  - The PI should only notify the local IRB if:
    There is a problem related to risk or other factors that impact the study.
  - A protocol change is needed.
  - The consent form requires revision.
- During Continuing Review, the PI should provide a DSMB safety report or AE summary.

Dr. Prentice also recommended that OHRP and FDA should promptly issue official guidance that is clear and consistent. This guidance should help research institutions/IRBs to interpret the Common Rule provisions that apply to the review of internal and external AERs.

Roadblocks and Advantages. Roadblocks to implementing this solution include the following:

- Pharmaceutical companies that sponsor research may object to a triage system in which AERs are not sent to all IRBs.
- Patient advocates may express concern over the lack of IRB involvement in AER review.
- The institution's legal counsel and/or PIs may have increased concerns about liability.

However, these are counterbalanced by the advantages, which include lower costs to pharmaceutical companies, research institutions, PIs, and IRBs. In addition:

- IRBs' workloads would be decreased and resources would be available for other activities.
- IRBs would no longer need "police" the review process, but could return to their intended role as of being part of an institutional team sharing responsibility for research oversight.

The Charge to SACHRP

Dr. Prentice charged SACHRP with determining what the Committee could do to facilitate OHRP/FDA's current efforts to develop guidance on AE reporting that protects

human subjects and provides relief from the AER burden. He suggested that beneficial guidance be drawn from the comments of philosopher and physician Henry Beecher. In 1966, Dr. Beecher noted that the two most important components of ethical research using human subjects are: (1) informed consent and (2) the safeguard provided "by the presence of an intelligent, informed, conscientious compassionate, responsible investigator."

SACHRP Discussion of External AERs
(NOTE: Dr. Khin-Maung-Gyi chaired this discussion.)

Dr. Fisher thanked Dr. Prentice for his presentation. She noted that the proposed system makes funders ultimately responsible for providing information about patient protections, but gives PIs responsibility for making decisions about what is done with this information. She asked whether the PIs were qualified to make these decisions, and she observed that, for this system to work properly:

- Sponsors would aggregate data and report it to independent DSMBs.
- The DSMBs would send the data to the PIs.
- The PIs would apply established criteria to determine whether to inform the IRB.

Dr. Prentice agreed that this would be the ideal system, but implementation would require changing regulations. In contrast, Dr. Prentice's proposal would not require regulatory changes. Accountability would rest with the PIs; although they receive limited information, they are better positioned than the IRBs to decide whether action is needed. When PIs decide no action is needed, the data and their supporting analyses are filed. If action is needed, the data is forwarded to the IRBs. Dr. Fisher expressed concern that PIs and DSMBs would have different criteria for determining whether AEs were serious and warranted protocol changes. Dr. Prentice agreed that this was a legitimate concern.

Ms. Kornetsky commended Dr. Prentice and observed that many IRBs already are using his proposed system to facilitate review. She suggested that PIs should provide IRBs with data safety management plans (DSMPs) and establish DSMBs. She also asked that IRBs add special DSM criteria to protect vulnerable populations. Dr. Prentice agreed with the latter stipulation, but noted that DSMBs do not operate in real time. Ms. Kornetsky and Dr. Prentice agreed that a mechanism would need to be put in place to ensure that potentially serious problems were reviewed quickly by DSMBs.

MOTION:

> Dr. Hauser moved that the Committee recommend to the DHHS Secretary that OHRP and FDA should issue official guidance that facilitates the ability of research institutions/IRBs to interpret and apply 45 CFR 46.103(b)5 and 21 CFR 56.108(b)1 to the review of internal AERs and external AERs. He added that the final wording of the motion also should convey SACHRP's sense of urgency about this. The word "promptly" might be inserted before "issue official guidance …" in the recommendation.

DISCUSSION:

Mr. Adams asked whether SACHRP should establish a Subcommittee to study the AER problem. Dr. Prentice observed that resolving the AER issue is a high priority. Both OHRP and FDA have been given copies of this presentation and additional information. Using the Subcommittee process would take a great deal of time and is not likely to provide additional important information for consideration by OHRP and FDA.

Dr. Khin-Maung-Gyi asked OHRP and FDA for any comments on the motion. Dr Schwetz stated that OHRP is prepared to move on this issue as a high priority. Dr. Lepay noted that FDA is prepared to move ahead with the aspects of AERs that apply to IRBs.

ACTION:

Mr. Adams seconded the motion. SACHRP accepted the motion unanimously.

Continued SACHRP Discussion of AERs (1)

Dr. Lepay explained that Dr. Prentice's proposal appears to comply with existing FDA regulations. Dr. Prentice reported that this model is being used at the City of Hope and at the University of Washington. Dr. Weiner and Mr. Adams noted that PIs may have conflicts of interest regarding defining and reporting serious AEs. Drs. Khin-Maung-Gyi and Prentice explained that OHRP and FDA guidance will address this issue. Dr. Fisher recommended that PIs provide the IRB with: (1) assurances that an independent DSMB will be used and (2) plans for its operation in various circumstances. Dr. Prentice reviewed the proposed AER process, focusing on the following points:

- The PI must analyze each AER provided by the sponsor/DSMB; this includes determining whether the risk/benefit ratio has changed and providing a supporting rationale for the decision.
- All of the AERs not sent to the IRB are filed and audited.

Public Comment

John Mather, M.D.

The Director of the Office of Compliance Review at the University of Michigan, Dr. Mather commended SACHRP on the AER recommendation. He asked that potential PI conflicts of interest be carefully reviewed, noting that these might be considerable when the PI is an employee of the company sponsoring the research. Dr. Mather also suggested that the SACHRP meetings include more frequent public comment sessions.

Paul Goebel, CIP

Mr. Goebel, Vice President, Chesapeake Research Review, Inc.,suggested that the informed consent documents be modified to help patients understand that they have options other than suing to resolve liability issues. Mr. Goebel also commended SACHRP for the AER recommendation and suggested that the guidance clearly explain to sponsors that not every AER must go to the IRB.

Maura Keen, University of Minnesota

Ms. Keen, although not speaking in her official capacity, did make comments based on her experiences supervising IRBs at the University of Minnesota. She urged SACHRP,

OHRP, and FDA to provide guidance concerning how to advise research sponsors from the pharmaceutical industry that ask for IRB reviews with the goal of obtaining protection from potential liability. She also asked the three governmental entities to provide guidance regarding international research conducted in Canada and other developed countries.

Continued SACRHP Discussion of AERs (2)

Dr. Khin-Maung-Gyi observed that FDA has asked IRBs to review IND safety reports for potential human subject safety issues. However, IRBs are not able to serve as DSMBs. The forthcoming guidance should be viewed as an opportunity to clarify the roles of various entities in protecting participants.

In response to a question from Dr. Prentice, Dr. Khin-Maung-Gyi explained that when an independent IRB is selected as the Board of record for a multi-center study, it can apply economies of scale to reviews. However, much like academic IRBs, the independent Boards may have difficulties obtaining and interpreting data from distant locations.

Dr. Prentice noted that PIs are increasingly more likely to address AEs by modifying consent documents rather than modifying the protocol. Mr. Barnes cautioned against cluttering the consent form with language referring to risks that are not truly significant. He explained that only items meeting the standard of significant risk should be included in the consent form.

Review of Previously Discussed Action Items

Dr. Prentice summarized some of the near-term action items to be undertaken by the Subcommittees and SACHRP:

- The Pediatrics and Subpart C Subcommittees will meet to address their respective goals, as laid out on Monday, March 29.
- SACHRP will send a letter to HHS Secretary Thompson recommending the adoption of the non-FAC model for pediatric 407 reviews once the language has been crafted. This wordsmithing will be done by Dr. Fisher and Ms. Kornetsky using the minutes from this meeting and consulting with other SACHR members as needed. The 407 algorithm recommendation crafted by SACHR at the December meeting will be incorporated in this letter.
- The Accreditation Subcommittee's final report will be sent to the Secretary.
- The recommendation on AERs, supplemented with language explaining the growing burden on IRBs, will be sent to the Secretary. This information might be made into a report and sent with the Accreditation report and the pediatrics recommendations.
- Mary Lake Polan and Melody Lin will be contacted regarding a timeline for addressing international research issues.

Litigation Issues

SACHRP agreed to address the litigation issues summarized by Dr. Morreim. Mr. Barnes asked that SACHRP make any recommendations requiring Congressional action before the November elections. Dr. Prentice observed that no IRB has been successfully sued. He

explained that the real impact of current litigation is on paperwork: documentation requirements are steadily increasing because research institutions take a defensive posture regarding possible suits. Other comments included the following:

- Dr. Jones suggested broadening the scope of SACRHP's discussion to include more legal risks to PIs as well as IRBs.
- Dr. Hauser asked for more data regarding litigation.
- Dr. Fisher said that Dr. Morreim did not provide actionable recommendations.
- Mr. Adams suggested that SACHRP should avoid becoming involved in potentially controversial issues best addressed by other groups.
- Members of the public provided anecdotal evidence that PIs are increasingly facing problems obtaining liability insurance.
- Based on the foregoing conversation and the magnitude of the issues involved, Mr. Barnes recommended not pursuing litigation/liability issues at this time.

It was agreed that consideration of litigation would be postponed. SACHRP will recommend that the IOM Clinical Research Roundtable review litigation issues.

MOTION:

A motion was made and seconded stating that the information presented by Dr. Morreim as well as the ensuing questions and answers, should be summarized and presented to the IOM Clinical Research Roundtable.

ACTION:

SACHRP passed the motion unanimously.

Endorsement of the AAMC Recommendations Presented by Ms. Ehringhaus

Dr. Fisher asked that SACHRP endorse the AAMC recommendations found in Ms. Ehringhaus' presentation. The endorsement should include language explaining that these recommendations would help clarify and resolve Privacy Rule/Common Rule issues that otherwise would become unduly burdensome to OHRP and SACHRP in their deliberations. Mr. Barnes suggested that the recommendations be endorsed by SACHRP and then be amplified by interested SACHRP members, including himself. Dr. Prentice explained that SACHRP rules did not allow this. Ms. Kornetsky suggested that a group of SACHRP members draft a letter for consideration at the next meeting. SACHRP accepted this suggestion.

Tissue and Data Repositories

Noting that OHRP receives many questions concerning tissue and data repositories, Dr. Prentice proposed that the SACHRP address these issues. Ms. Kornetsky reported that a group of attendees at the upcoming Public Responsibility in Medicine and Research (PRIM&R) conference plan to draft a document pertaining to tissue and data repositories. Several SACHRP members will assist in drafting that document, which is to be ready in October. Dr. Prentice suggested that SACHRP defer discussion of this issue until after the PRIM&R document is presented this fall. At that time, it could become a platform for SACHRP discussion. The members agreed.

Defining Research

Dr. Prentice noted that it is becoming more difficult to determine what qualifies as research. This issue, which has become a challenge for OHRP, is being addressed by the Hastings Center. SACHRP members reported that the Center is looking at the issue from a perspective that might leave some SACHRP and OHRP concerns unaddressed. Dr. Schwetz reported that defining research, especially for public surveillance and quality assurance studies, is an on-going issue for OHRP. Ms. Kornetsky observed that defining research is an issue for many Federal agencies.

MOTION:

Ms. Kornetsky moved that a panel be developed to speak at the next SACHRP meeting. Mr. Barnes seconded the motion.

DISCUSSION:

Mr. Barnes recommended inviting Erin Mellon and Jeremy Sugarman to join the panel. Both of these individuals are experts in the field and have recently published articles on the topic in scholarly journals. Dr. Fisher suggested that a representative of the American Educational Research Association (AERA) also be invited to speak.

ACTION:

SACHRP approved the motion with one abstention (Felix Khin-Maung-Gyi).

Applying a Biomedical Model to Behavioral and Social Science Research

Dr. Prentice noted that concern about this issue, especially related to IRB reviews, is growing. Dr. Fisher added that a special concern in behavioral science research is defining "minimal risk." Dr. Prentice suggested that Joan Seiber be asked to join any panel discussing this issue.

Dr. Fisher remarked that minimal risk should be jointly discussed by the Subpart C and D Subcommittees with attention paid to the implications of Subpart A. She added that it might be appropriate for SACHRP to develop an agreed-upon definition with any needed modifications for all of the Subparts, before discussing:

- An appropriate definition for use in behavioral research
- Other issues related to behavioral research.

Dr. Prentice observed that it might be effective to address the confusion in Subpart A related to minimal risk by using remedies that do not require notification of policy-making, but are based on the clear intent laid out in the 1981 Preamble to the FDA and HHS regulations. Ms. Odwazny explained how this might be done. Ms. Kornetsky added that minimal risk determinations made to clarify Subpart A might also be applied to Subpart D. Ms. Odwazny cautioned that defining minimal risk for the various Subparts would require a careful review of the regulations.

Conflicts of Interest (COI)

Dr. Prentice observed that institutions are making progress in addressing COI issues. He suggested that SACHRP wait until the institutions are further along in modifying their COI

plans before determining what involvement might be appropriate for the Committee. The group concurred.

Decisionally Impaired Subjects

Dr. Prentice reported that OHRP is discussing how best to address issues related to the participation of decisionally impaired subjects in research. Dr. Khin-Maung-Gyi proposed postponing SACHRP discussion until OHRP had made further progress in its deliberations about including decisionally impaired subjects in research. Ms. Kornetsky asked that OHRP inform SACHRP about when it might be appropriate for the Committee to open this discussion. The members agreed to the proposals made by Dr. Khin-Maung-Gyi and Ms. Kornetsky.

Subpart B

Dr. Prentice noted that Subpart B may need to be rewritten. At a minimum, several issues, such as whether pregnant women have appropriate protections, need reconsideration. Mr. Barnes suggested that Drs. Polan and Jones, who have experience related to Subpart B, make a presentation on this issue. Dr. Jones explained that an analysis of Subpart B involves discussing many issues, including:

- How to define research vis-á-vis new fetal procedures
- Liability concerns related to subjects who become pregnant while participating in studies
- Whether human research protections should be extended to embryos.

Drs. Prentice and Jones agreed that the term "embryo" as used in Subpart B, needs to be clarified. However, added Dr. Jones, this should not be an issue for SACRHP.

MOTION:

SACHRP members asked Drs. Polan and Jones to present a Subpart B panel.

DISCUSSION:

It was agreed that Drs. Polan and Jones will develop an agenda for review that might include guest speakers.

ACTION:

SACHRP unanimously approved the motion.

Third Subcommittee

No third Subcommittee currently exists. One may be created at the July meeting.

July SACHRP Meeting

The next SACHRP Meeting will be held on July 26 and 27 at the Sheraton Four Points Hotel in Washington, D.C.

Other Issues

NIH Collaborative Review of HRP Regulations

Ms. Kornetsky raised questions about a press article reporting on an initiative at NIH to lead a collaborative review of Federal human subjects regulations; this review is an

initiative of the NIH Roadmap and involves a range of issues of concern to NIH. She asked for more information on this review so that SACHRP could avoid duplicative efforts. Drs. Shore and Schwetz explained that this review evolved on a piecemeal basis from the NIH roadmap initiative. Dr. Amy Patterson, Director, Office of Biotechnology Activities, Office of Science Policy, NIH, discussed the initiative at the last SACRHP meeting. Dr. Shore added that:

- The current focus of the review is on regulatory differences between FDA and OHRP and inconsistent clinical research policies within NIH. Attention is not being paid in any specific way to Subparts C and D of 45 CFR 46.
- The deliberations and recommendations of SACHRP are of interest and relevance to these efforts.

Drs. Khin-Maung-Gyi and Jones asked for more information about the review and regular updates on the members' progress.

Minimal Risk

Ms. Kornetsky noted that the pediatrics Subcommittee has been moving toward an absolute definition of minimal risk that might be inappropriate given that this issue must be addressed in a larger context. Ms. Odwazny will discuss this issue with OHRP and provide additional information to aid in Subcommittee discussions. Dr. Fisher asked that the Subcommittees be regularly updated by OHRP's legal advisors concerning limitations that apply to their deliberations. She asked that a representative of the legal staff be present at all Subcommittee and Committee meetings.

Adjournment

Dr. Prentice thanked members of SACHRP and the public for their participation. Based on the performance of SACHRP and the Subcommittees thus far, he predicted that the July meeting would be fruitful and exciting.

Secretary's Advisory Committee on Human Research Protections
Meeting
March 29-30, 2004
Alexandria, VA

ACTION ITEMS*: Monday and Tuesday*

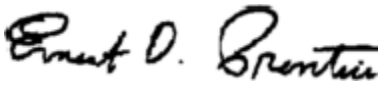
1. A single set of recommendations is to be crafted by the Subcommittee on Research Involving Children and OHRP and incorporated in the meeting minutes.
2. Nominations for SACHRP positions should be sent to Catherine Slatinshek, Executive Director, SACHRP.
3. The Subcommittee on Subpart C will:
   - Prepare recommended short and/or intermediate-term solutions for the July 2004 SACHRP meeting.
   - Obtain additional legal input about providing special protections to individuals not at high risk for incarceration who enroll in a study and then are incarcerated.
4. SACHRP will send a letter to HHS Secretary Thompson recommending the adoption of the non-FAC model for pediatric 407 reviews once the language has been crafted. This wordsmithing will be done by Dr. Fisher and Ms. Kornetsky using the minutes from this meeting and consulting with other SACHRP members as needed. The 407 algorithm recommendation crafted by SACHRP at the December meeting will be incorporated in this letter.
5. The Accreditation Subcommittee's final report will be sent to the Secretary.
6. The recommendation on AERs, supplemented with language explaining the growing burden on IRBs, will be sent to the Secretary. This information might be made into a report and sent with the Accreditation report and the pediatrics recommendations.
7. Mary Lake Polan and Melody Lin will be contacted regarding a timeline for addressing international research issues.
8. Mr. Barnes and Ms. Kornetsky will prepare a document based on the [presentation by Dr. Morreim and the ensuing SACHRP discussion. This document will be given to Dr. Schwetz to present to the IOM Clinical Research Roundtable.
9. At the July 2004 meeting, Susan Kornetsky and Mark Barnes will report on appropriate amplifications that should be made to the AAMC recommendations prior to possible endorsement by SACHRP.
10. SACHRP will address issues relating to tissue and data repositories after reviewing the document produced by PRIM&R this fall.
11. OHRP, in consultation with SACHRP members, will begin work on a panel to discuss what constitutes research. The panel will be convened at the July OHRP meeting.
12. SACHRP put the discussion of COI on hold until the research institutions are further along in modifying their plans.

13. SACHRP agreed to postpone its discussion of including decisionally impaired subjects in research until notified by OHRP that the Office had made further progress in its deliberations on the topic.
14. Drs Polan and Jones will present a Subpart B panel. As the first step, they will develop an agenda for review that might include guest speakers.
15. Dr. Shore is to send SACHRP a roster of members of NIH's HRP review group and copy of the group's mandate.
16. Ms. Odwazny will discuss the regulations regarding "minimal risk" with OHRP and provide additional information to aid in Subcommittee C and D discussions

Secretary's Advisory Committee on Human Research Protections
Meeting
March 29-30, 2004
Alexandria, VA

Certification of the Summary of Minutes

I hereby certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.



Ernest D. Prentice, Ph.D., Chair Date