DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Secretary's Advisory Committee on
Human Research Protections
Washington, DC 20201

September 18, 2008

The Honorable Michael O. Leavitt
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

In accordance with the provisions of the charter for the Secretary's Advisory Committee on Human Research Protections (SACHRP), I respectfully submit for your consideration a set of recommendations relative to Department of Health and Human Services (HHS) human subjects protection regulations at 45 CFR part 46. These recommendations represent the eighth in a series of recommendations from SACHRP.

I. Recommendations Regarding Subpart A of 45 CFR Part 46

A. Background

On October 5, 2004**,** SACHRP approved a resolution establishing a Subcommittee on Subpart A. SACHRP's charge to the subcommittee was to review and assess all provisions of subpart A of 45 CFR part 46 (HHS' codification of the Federal Policy for the Protection of Human Subjects, also known as the Common Rule) and relevant Office for Human Research Protections (OHRP) guidance documents, and based on this review and ongoing assessment, to develop recommendations for consideration by SACHRP in three categories: (1) recommendations on interpretation of subpart A provisions; (2) recommendations for development of new, or modification of existing, OHRP guidance; and (3) recommendations for possible revision of subpart A.

The goals of this review and assessment of subpart A of 45 CFR part 46 are threefold: (1) to enhance the protection of human subjects; (2) to reduce, where possible, regulatory burdens that do not contribute to the protection of subjects in a meaningful way; and (3) to promote scientifically and ethically valid research. To that end, the

following recommendations regarding (1) the categories of research activities that are exempt from the requirements of 45 CFR part 46; (2) alternative models of institutional review board (IRB) review; (3) IRB membership rosters; (4) waiver of the documentation of informed consent; (5) institutional responsibilities and the role of institutional officials; and (6) research involving American Indian or Alaska Native populations were developed by the Subpart A Subcommittee, and discussed and approved by SACHRP at its meetings on October 29th, 2007, March 27th, 2008 and July 16, 2008.

B. Exemptions – Recommendation for Consolidated Guidance

Need for Consolidated Guidance. OHRP should develop a consolidated, comprehensive guidance document on the implementation of the provisions under HHS regulations at 45 CFR 46.101(b) for exemption of research from the requirements of 45 CFR 46. The guidance should address both general issues impacting the application of the exemption categories and specific guidance for each of the six existing exemption categories.

C. General Recommendations That Apply to All Exemption Categories

(1) Relationship between the Exemptions and the Definitions of "Human Subject" and "Research." Institutions and investigators are still confused about the decision steps for determining the applicability of the HHS regulations prior to making exemption determinations. Some activities that do not meet the regulatory definition of "research" (45 CFR 46.102[d]) or "human subjects" (45 CFR 46.102[f]) are inappropriately reviewed through use of the exempt categories. The guidance should clearly state the sequence and interrelationships between the definitions of "research" and "human subject" with the exemptions.

It would also be helpful for OHRP to cross-reference and incorporate elements from their existing "Guidance on Research Involving Coded Private Information or Biological Specimens" (dated August 10, 2004), which helps make this distinction and provides relevant examples.

(2) Relationship between Exemptions and Expedited Review Categories. The guidance should clearly state the sequence and interrelationships between the exemptions under 45 CFR 46.101(b) and the expedited review process, especially when categories of research activities eligible for exemption and the categories of research eligible for review under an expedited review procedure address similar research methods. Examples should be used including research with focus groups, video taping, specimens, etc. These examples should compare the exempt and expedited categories that might apply to the example activity.

(3) Subpart D Limitations. The guidance should address the limitations placed on the applicability of the exemption category at 45 CFR 46.101(b)(2) by subpart D of 45 CFR part 46 for research involving children.

Furthermore, to assist institutions and researchers, any other federal agencies that have adopted the subpart D limitations should be listed (e.g., U.S. Departments of Education and Homeland Security). In addition, any differences between 45 CFR part 46 and other agency regulations should be noted (e.g., Food and Drug Administration (FDA) regulations, which do not include exemption categories).

(4) Institutional Mechanisms for Making the Determination of Exempt Status. It is appropriate for institutions to put in place mechanisms for making determinations that research is exempt from the federal regulations. The guidance should retain the current OHRP interpretation, which recommends that institutions have policies in place that designate the individual(s) or entity(ies) with the authority to determine whether human subjects research qualifies for exemption under HHS regulations at 45 CFR 46.101(b). This individual or entity can be any knowledgeable and appropriately trained person designated by the institution and does not have to be affiliated with the IRB. The guidance also should reiterate the current OHRP recommendation that investigators should not be given the authority to make an independent determination that their own human subject research is exempt.

(5) Application of Regulatory Standards to Exempt Research. The guidance should make it clear that, if research is determined to be exempt under 45 CFR 46.101(b), the regulatory provisions in the remainder of 45 CFR part 46 do not apply. Examples of regulatory provisions that are not required to be applied if research is certified as exempt include: review by the convened IRB; expedited review; continuing review; IRB review of informed consent process; and IRB review of documentation of informed consent, assent, or parental permission (i.e., consent/permission/assent forms). IRB review is not required because these protections are generally not warranted for exempt research, it weakens the line of responsibility of investigators, and it drains resources from regulation-required activities.

(6) Application of Ethical Principles to Exempt Research. Even when research is exempt from regulatory requirements under the Common Rule, institutions and investigators still have a responsibility to adhere to the underlying ethical principles for research involving human subjects.

(7) Assessment of Risk. The 1981 Preamble to 45 CFR part 46 states that an underlying assumption of the exemption categories is that the research is of “little or no risk”. Although the Common Rule does not specify the meaning of “little or no risk,” most institutions interpret this to mean “not greater than minimal risk.” Even though the regulations do not require the institution to assess the risk of proposed exempt research, OHRP should recommend in its guidance that research conducted under the exempt categories be determined to be no greater than minimal risk.

OHRP guidance should acknowledge that different agencies have different interpretations and institutions are cautioned to ensure compliance with those agency

interpretations when reviewing/conducting studies funded/governed by those agencies.

(8) Independent Application of Categories. One area of current difficulty in application of the exemption categories occurs when studies that are exempt under the category at 45 CFR 46.101(b)(1) use techniques such as surveys or interviews that are addressed in the category at 45 CFR 46.101(b)(2). If an activity satisfies the requirements for any one exempt category, it may be deemed exempt. The guidance should include examples clarifying this interpretation.

- A student teacher designs a research project to compare teaching strategies employed by two teachers in her practice school and her data collection method is surveys of the students and interviews with the teachers. This research might be contrasted with an example where the exemption at 45 CFR 46.101(b)(1) could not be used, but another category could be, e.g., a survey study of graduate students that asks about drug use behavior. While the survey may take place in a commonly accepted educational setting, the research topic/activity (the drug use survey) is not a "normal educational practice." The guidance should make the point that, just because research happens in a school, this does not make it automatically exempt. Conversely, research that is exempt under a category other than 45 CFR 46.101(b)(1) can be conducted in educational settings even if they do not study educational practices.

- Student teachers are often trained by observing classroom activities, participating in activities, or a combination of the two. A research study using observations/ratings of skill levels at points in the training of student teachers who are learning with the different methods could be designed. The guidance should address the following questions: How do the exemptions at 45 CFR 46.101(b)(1) and (2) interface in this example? What if the observation includes an assessment of stress levels (student teachers and children)? What if surveys or interviews are used?

(9) Removal of Subpart C Limitations. Many research opportunities afforded to general populations should be available to prisoners; therefore, permitting the application of the exemptions to research involving prisoners should be part of the redrafting of the HHS regulations at Subpart C of 45 CFR part 46, especially when the current provision under 45 CFR 46.306(b) is considered. The language in the restrictive footnote to 45 CFR 46.101(b) regarding the prohibition against applying the exemptions to research involving prisoners should also be removed.

D. Recommendations Pertaining to Exemption Category 1 - This category includes: § 46.101(b)(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(1) Clarification of Terms. The terms "established" and "commonly accepted educational settings" and "normal educational practices" should be clarified through the use of examples and defining characteristics.

The guidance should include the current OHRP interpretation of the terms "established" and "commonly accepted educational setting" as including nontraditional settings such as a grocery store (e.g., nutrition class), a pharmacy, or automotive garage (e.g., safe driving or how to do preventative maintenance on a car), as long as the educational setting is established in the local area. The OHRP guidance clarification should include additional examples to clarify what a "commonly accepted" educational setting is such as: evaluation of resident training; hospital grand rounds; professional conferences; home school; land-grant extension agents providing training in the farm setting. Examples are also needed to clarify what qualifies as an "established setting."

- The guidance clarification/examples should also address international and cultural differences. For example, if the educational practice is commonly accepted in a specific population such as Amish or Native Americans, it should be considered "commonly accepted" for research within that population.

- The guidance also should provide the current OHRP interpretation of "normal educational practices" as not being restricted to only traditional approaches in traditional settings, but may include such practices as computerized training, the use of a kiosk to provide education, or using a software program to study the education of non-English speaking students on learning English. The guidance should expand upon the definition with some additional examples and should clarify that determining whether the research uses "normal educational practices" is distinct from the determination whether the setting is "established" or "commonly accepted."

(2) Other Examples. Guidance should clarify whether and when "action research" (for example, community-based participatory research) is eligible for exemption. These types of activities usually are designed to contribute to generalizable knowledge; however, the development of the study plan (protocol) does not follow the "traditional" model. The study plan develops as part of the interaction with the community and/or subjects. One major issue with this type of research is whether consent needs to be obtained. The Guidance should use examples to illustrate when actions or community-based participating activities do not meet the definition of research, fit under one or more exemption categories, or are eligible for IRB review under an expedited review procedure.

(3) Other Agency Rules. OHRP guidance should note if this exemption does not apply to research regulated by other agencies.

E. Recommendations Pertaining to Exemption Category 2 - This category includes: § 46.101(b)(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and** (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(1) Examples Needed. The guidance should provide examples of each of the types of activities included in this exemption: educational tests, survey procedures, interview procedures, and observation of public behavior.

Guidance should include the current OHRP interpretation of "public behavior" as being behavior generally open to view by any member of a community and/or which would not involve any special permission to observe (i.e., no reasonable expectation of privacy by those being observed), such as, at a park, in a mall, at a movie theater, etc. The guidance also should provide the OHRP interpretation that what occurs in a classroom would not generally be considered observation of public behavior. Consistency across agencies is essential to effective regulatory compliance, and OHRP guidance should resolve or explain any interdepartmental differences in interpretation of the applicability of the exemption at 45 CFR 46.101(b)(2).

Including examples and clarification in the guidance about research methods that are not specifically listed in the exemption regulations, but that may qualify for exemption, would also be useful. OHRP guidance should use examples to show how a research method fits into this category or when it does not meet the definition of research. These methods include: focus groups; ethnography; oral history.

OHRP should revise its current interpretation to indicate that audiotape information alone does not, based solely on the medium, constitute private identifiable information. On the other hand, there may still be times when audiotapes are identifiable, depending on the circumstances (e.g., limited size sample, unique voice characteristics, recognizable participants).

The guidance should include examples illustrating what "through identifiers linked to the subject" means. Examples would also be useful to illustrate what "readily ascertained" means and expand upon contextual considerations that may be relevant to ascertaining identity.

Examples should be included in the guidance that illustrate when research activities could "be damaging to the subjects' reputation."

(**2) Clarification Needed.** The guidance should emphasize the use of the conjunction "and" in the wording of the exception to this exempt category and provide examples outlining when this exception is and is not applicable.

(3) Risk Determination. The guidance should clarify that the nature of the survey or interview questions impacts the applicability of this category. Examples of activities with greater than minimal risk should be used to show when the exemption should not apply.

(4) Regulatory Limitations. Subpart D limitations would be discussed in the general section but, for emphasis, should be referred to under this heading also. OHRP should list agencies that did not adopt exemptions for children (e.g., FDA).

F. Recommendations Pertaining to Exemption Category 3 - This category includes the following: § 46.101(b)(3): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(1) Examples needed. The guidance should include examples of "public officials." In particular, the guidance should include examples that OHRP has provided in the past, such as university faculty, public school teachers, and police officers in general are not considered to be elected or appointed public officials, whereas mayors, governors, school superintendents, school board members, and police chiefs are considered to be elected or appointed public officials.

(2) List Statutes. The guidance should specifically list examples of federal statutes that meet the criteria outlined in (ii). The guidance needs to clarify that this category does not apply to state law.

(3) Other Agencies. OHRP should point out whether this exemption applies to research regulated by other federal agencies.

G. Recommendations Pertaining to Exemption Category 4 - This category includes the following: § 46.101(b)(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(1) Examples/Clarification. Guidance should provide clarification with corresponding examples that address the following terms:

- "Existing": Guidance should retain the current OHRP interpretation on what constitutes "existing" data, etc. Guidance should include a clarification that the definition of "existing" is dependent upon when the study is determined to be exempt by the institution. The rationale for OHRP's long-standing interpretation

- of the meaning of "existing," which was articulated in the 1993 IRB Guidebook, should be included in the updated guidance. Guidance should specifically state that data obtained prospectively does not qualify for exempt review.

- "Publicly available": Guidance should provide examples and discussion regarding what constitutes publicly available data (e.g., telephone directories). For example, do discussions in on-line blogs or internet sites (e.g., MySpace, Facebook or other networking sites) meet the publicly available criterion? Guidance should cite examples of data that are not publicly available, especially providing examples that are not publicly available due to federal legislation (e.g., student records and the Family Educational Rights and Privacy Act).

- "Recorded": Guidance should clarify that a researcher can view identifiers, but if the identifiers are not recorded in the research data/records, the study may still be exempt. Guidance also should address overlaps and inconsistencies between the HIPAA Privacy Rule and 45 CFR part 46.

- "Cannot be identified directly or through identifiers linked to the subjects": Guidance should include examples of direct and indirect links such as hospital numbers, codes, or links that tie dates back to the list of subjects.

  One helpful example that OHRP has used in the past is that exemption category 45 CFR 46.101(b)(4) applies to a retrospective chart review where the researcher records the dates of medical procedures, unless the dates of medical procedures would allow investigators to identify subjects.

(2) Sequencing. Reference should be made in the guidance to the sequence of determinations addressed under Recommendation 2 above (i.e., definition of human subject, the exemption at § 46.101(b)(4), and the applicability of the expedited review categories).

(3) Other Agencies. OHRP should point out whether this exemption applies to research regulated by other federal agencies.

H. Recommendations Pertaining to Exemption Category 5 - This category includes the following: § 46.101(b)(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Background for Recommendations on Exemption Category 101(b)(5)
OHRP has issued a guidance document on this exemption entitled "Exemption for Research and Demonstration Projects on Public Benefit and Service Programs." It states that unless the following criteria are met, the exemption cannot be invoked:

- The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
- The research or demonstration project must be conducted pursuant to specific federal statutory authority.
- There must be no statutory requirement that the project be reviewed by an IRB.
- The project must not involve significant physical invasions or significant intrusions upon the privacy of participants.

(1) Federal and state. Criterion (2) above is interpreted too narrowly and institutions should be able to apply this exemption to public programs supported by state departments and agencies as well as federally supported public programs. OHRP has explained that the broadening of the exemption is not possible within the constraints of the current regulations. When developing new guidance, OHRP should broaden its interpretation to include using the exemption for activities that involve federal flow-through monies to the state public benefit programs. Note that it would need to be made clear that state university research did not fit under an expanded exemption.

(2) Federal versus state. If it is not possible to broaden the interpretation of this exemption category, the guidance should specifically indicate that state programs do not fit under this category and list the federal programs with the statutory authority to fit in the category.

I. Recommendations Pertaining to Exemption Category 6 - This category includes the following: § 46.101(b)(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Clarification needed. This category is used inconsistently, and sometimes inappropriately, by the research community because it is not understood by institutions or researchers. Guidance should indicate that the category addresses two different types of research activity. Then each type of activity should be discussed in detail providing explanations regarding when this category can be used, delineating any corresponding regulations that apply, and discussing examples of studies that fit within the category.

J. Other Recommendations Relevant to Exemptions

The Secretary of HHS, acting in consultation with the Secretary of Education, should convene an interagency working group to draft a joint guidance document on the relationship between the Federal Policy for the Protection of Human Subjects (the

"Common Rule"), the Family Education and Rights Privacy Act, and the Protection of Pupil Rights Amendment. This workgroup should also address any differences in interpretations of the exemption requirements (e.g., definitions of educational settings, whether classroom activities are publicly available, etc.).

K. Recommendations Regarding Alternative Models of IRB Review

(1) SACHRP supports the efforts of the planning group for recent national conferences and initiatives (including representatives of OHRP, the National Institutes of Health [NIH], the Association of American Medical Colleges [AAMC], the American Society of Clinical Oncology, the Department of Veterans Affairs, and others) to keep the topic of alternative IRB models before the research community.

(2) SACHRP endorses the consideration and utilization of collaborative IRB models, appropriate to the circumstances of a given research scenario.

(3) OHRP should continue its efforts to develop guidance on IRB models. This guidance should include a sample "toolkit" (including SOPs and model agreements) for use by institutions that are considering review models other than review by the local IRB.

(4) SACHRP requests the HHS Secretary to encourage the NIH Director to explore more widespread use of collaborative IRB models, including expanded use of Centralized IRBs (CIRBs) for NIH-sponsored research.

L. Recommendations Regarding IRB Membership Rosters

(1) OHRP should interpret § 46.103(b)(3) to require that changes in IRB membership be reported to OHRP every three years (NOT every 90 days, as in current guidance)

(2) OHRP should pursue changing the Common Rule to harmonize with the FDA by eliminating the requirement to submit IRB membership rosters.

M. Recommendations Regarding Waiver of the Documentation of Informed Consent

(1) OHRP should provide guidance on the interpretation and application of § 46.117(c), using examples as appropriate, with particular emphasis on social or behavioral research. Additional resources should be provided to OHRP to educate IRBs on these provisions.

(2) With regard to § 46.117(c)(1), OHRP guidance should clarify that

- there would be no links between the subject and the research (e.g., investigator notes) other than the consent form itself;
- this provision is not limited to minimal risk research, and is appropriate for those studies that involve greater than minimal risk (e.g., some studies of domestic violence, illegal behavior); and
- what the term "documentation" used this section means**.**

(3) OHRP should clarify that the final sentence in § 46.117, regarding the provision of a written statement to subjects, applies to both (c)(1) and (c)(2).

(4) OHRP should clarify that, when the IRB requires a written statement as described under § 46.117(c), the statement does not need to include the elements of consent required under § 46.116 as long as the elements are addressed orally.

This guidance should include examples of situations where the IRB may choose to require a written a statement.

OHRP should also clarify that, if some of the elements of consent are not presented either orally or in writing, the criteria for waiving consent under § 46.116(c) or (d) must be met.

(5) OHRP should explore options for modifying or accommodating the requirement under § 46.117(c) (1) that each subject will be asked whether they want documentation linking them to the research, including the possibility of a Secretarial waiver of this requirement.

N. Recommendations Regarding Institutional Responsibilities and the Role of Institutional Officials

(1) Given the key role in human research protections played by Institutional Officials (IOs), OHRP should continue and strengthen its efforts to reach this group through training, outreach, and guidance. HHS should provide additional resources to OHRP to achieve this goal. Among other approaches, this includes outreach through professional organizations more likely to encompass IOs who may not participate in "IRB-related" venues, conferences and organizations (e.g., the National Council of University Research Administrators, the Council on Governmental Relations, the Association of American Universities, AAMC, the Consortium of Social Science Associations, et al).

(2) OHRP should develop standard nomenclature and definitions for terms that are currently used~~,~~ such as:

- "Organization"
- "Institution"
- "Organizational Official"
- "Institutional Official"
- "Signatory Official"
- "Head Official"

(3) OHRP should continue to define the IO as the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance. This individual should have the authority and responsibility to provide adequate resources to maintain an effective Human

Research Protection Program (HRPP). It is recognized that, within some organizational structures, these responsibilities may reasonably be executed by someone other than the chief executive officer, president or counterpart, in order to ensure an active, knowledgeable role for the IO in the HRPP.

(4) OHRP should develop expanded guidance on the expectations and responsibilities of IOs, including their ethical and regulatory obligations, and highlighting issues of both authority and autonomy. The guidance should recognize that some operational functions may be appropriately delegated by the IO; to the extent that selected obligations should not be delegated, these should be identified. This guidance might take the form of a simple bulleted list (draft example provided).

(5) OHRP should provide periodic (e.g., annual) reminders to IOs that reinforce their central role and responsibilities in human research protections, including the guidance recommended above. These reminders might be accomplished easily using e-mail contacts on file with OHRP through the Assurance process.

O. Recommendation Regarding Tribal Authority Over Research Involving American Indian or Alaska Native Populations

SACHRP recommends that HHS promote the development of guidance and grants policy in consultation with OHRP, other staff and operating divisions, and other appropriate Departments and agencies that address research involving American Indian or Alaska Native (AIAN) populations.

This guidance might address general issues that would be of interest and value to any investigators considering research with these populations. Specific issues to be addressed shall include the requirement for Tribal approval for research that is to be conducted within the jurisdiction(s) of federally-recognized AIAN Tribal government(s). Such approval shall come from the Tribal Council or other agency of Tribal government to whom such authority has been delegated by the Council. The requirement for Tribal approval shall be reinforced through educational outreach, and through the terms and conditions of HHS grants supporting such research, as a matter of grants policy.

II. Recommendations Based Upon SACHRP Panel "Issues Involving Research in Disaster Settings"

A. Background

On October 30, 2007, SACHRP was addressed by a panel discussing issues involving research in disaster settings. In response to this panel, SACHRP formed an ad hoc subcommittee which developed the following recommendations, later approved by SACHRP.

B. Recommendations

(1) Research involving humans in the aftermath of disasters is of critical importance; HHS should proactively recognize this and promote planning for the ethical conduct of such activities at the Federal, State and local levels.

(2) The ethical conduct of such research remains paramount, yet there appears to be no specifically identified, organized, coordinated, and time-sensitive process at the Federal, State and local level to ensure that:

- research activities following disaster events are conducted ethically, and
- opportunities to obtain useful generalizable knowledge, e.g., knowledge that might improve preparedness and response to the current or future disasters, are not lost due to the lack of workable mechanisms for prior review and coordination.

HHS should conduct an assessment of the current ethical review process and, if indicated, the feasibility of developing additional processes through its relevant components including, but not limited to, the Office of the Assistant Secretary of Health, the Office of the Assistant Secretary of Preparedness and Response, NIH, the Centers for Disease Control and Prevention, and FDA.

Key considerations in a feasibility assessment of a process for ethical conduct of disaster-related research should include the following:

- A plan for efficient review and approval at the Federal, State, and local levels for human subjects research activities following a disaster event;
- Evaluation of whether additional exemptions or waivers from human subjects protections regulations for certain types of low risk research are warranted in disaster-related research and whether an efficient process for obtaining such exemptions and waivers needs to be developed and implemented; and
- Appropriate criteria for State and local coordination and oversight of research activities in conjunction with disaster response activities. In particular, coordination and oversight should be sensitive to potential for research adversely impacting disaster management.

In conducting its preliminary assessment HHS should seek input from other relevant departments and agencies at the Federal, State and local levels as well as from other stakeholders through internal discussions and public venues sponsored by HHS and its components.

III. Recommendation Regarding the Review of the Human Subjects Protections System

A. Background

On July 16, 2008 SACHRP members had on open discussion focused on the desirability for a complete major or minor overhaul of the current human subjects protections system infrastructure. Issues addressed included the vision for a new model of human subjects protections; OHRP's central role in human subjects protections oversight; OHRP's vision and resources; and major problems currently facing the human subjects protections system. The goal was to identify key areas for future exploration, discussion, and recommendations on human subject protection activities.

B. Recommendation

The Department should explore opportunities for demonstration projects related to system-level changes as presented in the discussion.

A summary of the discussion, provided by the minutes, follows:

> Members noted many common elements among presentations, including the bias against exemptions, the need to make consent safeguards work, the need to disseminate best practices, and the need to appropriately address privacy risks. Dr. Tilden stressed the need to evolve a human subject protection system capable of assessing itself and making modifications. Other members emphasized the need for effective benchmarks to help identify projects that do not need review and standard forms that would enable programs to avoid wasting effort "reinventing the wheel."

Possible future directions include:

- Engaging other groups in addition to OHRP to develop best practices (the best forum remains to be determined);
- Developing demonstration projects that could contribute empirical data about the process of human subject protection; and
- Balancing compliance with proactive education and training.

Mr. Secretary, I trust you will find this report acceptable. Your committee members and SACHRP subcommittee members have worked hard in their pursuit of the charges contained in the charter. SACHRP has also worked closely with Dr. Ivor Pritchard and the rest of the OHRP staff and has benefited greatly from their expertise and leadership. We look forward to continuing our work and

providing you with recommendations which will enhance human subject protections and advance science for the benefit of all Americans.

Sincerely,

/S/ Julia Gorey, for

Samuel Tilden, M.D., J.D., L.L.M.
Chair, Secretary's Advisory Committee
on Human Research Protections

cc: Ivor A. Pritchard, Ph.D., Acting Executive Secretary, SACHRP
Julia Gorey, J.D., Executive Director, SACHRP