

Responses of
The Association of Academic Survey Research Organizations
To the Advanced Notice of Proposed Rule Making
Regarding the HHS Proposal to Improve Rules Protecting Human Research Subjects
October 2011

The Association of Academic Survey Research Organizations (AASRO), the leading voice in support and promotion of excellence in survey research conducted in academic settings, is very interested in the proposals to revise the federal regulations overseeing research involving human subjects. We represent survey organizations from both private and public universities, in every region of the United States. The organizations that we represent, and other academic survey organizations in the U.S. and elsewhere, share a common mission. We provide professional, scientific survey expertise and infrastructure to researchers inside and outside of academe. We share the government's concern that human subjects' protections remain our highest priority throughout the course of our research activities. Below, we offer our responses to the questions posed to the national research community by the Department of Health and Human Services. The points we address below are those about which we have the most expertise and about which we have reached a consensus which broadly represents the views of our membership.

I) Ensuring Risk-Based Protections

Calibrating the Levels of Review to the Level of Risk

Revise Approach to Expedited Review

AASRO is supportive of the proposed revisions designed to more finely calibrate levels of review with levels of risk and to relieve minimal risk research of as many administrative regulations as possible. Below, we address each relevant point raised about this issue.

Question 1: *Is the current definition of "minimal risk" in the regulations (45 CFR 46.102(i) -- research activities where "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests") -- appropriate? If not, how should it be changed?*

AASRO notes that problems have arisen with implementation of the "ordinarily encountered in daily life" criterion. The recruitment procedures inherent in the conduct of scientific surveys (e.g., cold calls, unannounced knocks on the door, refusal conversion) have been considered by some IRB members to be harassments that can cause discomfort beyond that ordinarily encountered in daily life. The definition should be clarified or refined, even though the new "Excused" category may specify classes of research methods that have the presumption of minimal risk, and therefore refinement of the definition may not be necessary for surveys and other related methods.

Question 2: *Would the proposals regarding continuing review for research that poses no more than minimal risk and qualifies for Expedited review assure that subjects are adequately protected? What specific criteria should be used by IRBs in determining that a study that qualifies for Expedited initial review should undergo continuing review?*

AASRO endorses the revised proposals regarding continuing review frequency for minimal risk research that qualifies for the Expedited category. We believe that these proposed revisions, which would eliminate the annual continuing review requirement for Expedited research, would not adversely affect subject protections, as investigators would continue to be required to immediately report adverse events. We do, however, recommend that a formal review process continue to be required to determine that data security risks (data sharing between organizations requiring transmission/transport of data, for example) are conducted with safeguards for data security and participant confidentiality.

Question 3: *For research that poses greater than minimal risk, should annual continuing review be required if the remaining study activities only include those that could have been approved under Expedited review or would fall under the revised Exempt (Excused) category described in section 3, below (e.g., a study in which a physical intervention occurred in the first year, all subjects have completed that intervention, and only annual written surveys are completed for the next five years)?*

AASRO also endorses the revised proposal that would eliminate the need for convened meeting review of protocols deemed greater than minimal risk but for which the only remaining study activities involve data analysis and/or follow-up. Again, this revision would be unlikely to have an adverse effect on subject protections given that remaining activities in these cases would be limited to those that are generally considered to pose minimal risks to research subjects.

Question 4: *Should the regulations be changed to indicate that IRBs should only consider “reasonably foreseeable risks or discomforts”?*

AASRO supports the proposal to revise regulations to indicate that IRBs should only consider “reasonably foreseeable risks or discomforts.” IRBs have been known to posit hypothetical risks that have extremely low probabilities of occurrence. Providing guidance that encourages IRBs to focus only on “reasonably foreseeable risks” would help protect subjects from higher probability risks and remove burdens on investigators to address very low probability risks.

Question 5: *What criteria can or should be used to determine with specificity whether a study’s psychological risks or other nonphysical, non-information risks, are greater than or less than minimal?*

AASRO believes it is not possible to adequately specify a single set of criteria for determining the degree to which a study’s psychological risks are greater than minimal that would be applicable to all research and that this may be most appropriately left to the determination of individual IRBs. One possibility for moving in this direction might be to create categories of clearly low risk and clearly high risk activities, leaving a gray zone of sorts that would be the purview of local IRBs to illuminate on a case-by-case basis. This would allow for larger clusters of research, such as opinion surveys, market research tests of preferences, customer/patient satisfaction or experience, program evaluation, health behavior surveillance, studies of voting behavior, etc., that would be clearly noted as low risk. Potential high risk areas could include such things as suicidal ideation, criminal behavior, or domestic violence. Clarifying these categories would lead to less variability in IRB determinations.

Question 6: *Are there survey instruments or specific types of questions that should be classified as greater than minimal risk? How should the characteristics of the study population (e.g. mental health patients) be taken into consideration in the risk assessment?*

Although AASRO does not believe that there is a preponderance of survey questions that would qualify as greater than minimal risk, it does acknowledge that there are some that will meet this criterion with certain populations under certain circumstances. Questions about suicidal thoughts or intentions, for example, may pose greater than minimal risk to members of psychologically vulnerable populations, but are likely to pose only minimal risk to most respondents in the general population. While we argue that survey research with competent adults is clearly minimal risk, IRBs must continue to take into consideration the intersection of the population being interviewed and the nature of the questions being

asked of them when making this determination for protected classes. For these cases, no one rule or standard will be appropriate for all circumstances.

Question 9: *How frequently should a mandatory review and update of the list of research activities that can qualify for Expedited review take place? Should the list be revised once a year, every two years, or less frequently?*

Although AASRO is in agreement that a mandatory review and update of the list of research activities that can qualify for Expedited review should take place on a periodic basis, our organization takes no position regarding the specific frequency of that review.

Question 10: *Which, if any, of the current criteria for IRB approval under 45 CFR 46.111 should not apply to a study that qualifies for Expedited review?*

AASRO sees no reason why the current criteria, as set forth in 45CFR46.111 should not continue to apply to research that is deemed eligible for Expedited review.

Question 11: *What are the advantages of requiring that Expedited review be conducted by an IRB member? Would it be appropriate to instead allow such review to be done by an appropriately trained individual, such as the manager of the IRB office, who need not be a member of the IRB? If not, what are the disadvantages of relying on a non-IRB member to conduct Expedited review? If so, what would qualify as being “appropriately trained”? Would the effort to make sure that such persons are appropriately trained outweigh the benefits from making this change?*

AASRO agrees that giving appropriately trained human subjects research professionals, in addition to IRB members, the authority to review and approve protocols that are considered eligible for Expedited review, may help to decrease the turnaround time needed for decisions on these protocols, at least at some institutions. In many instances, full-time human subjects research professionals are more educated and have more experience regarding the relevant issues than do part-time IRB members. We nonetheless agree that allowing non-IRB members to make final decisions regarding protocols would not be appropriate. One solution might be to stipulate that human subjects research professionals could be given the authority to approve Expedited applications only in those instances where they are also allowed to serve as a full member of the IRB.

Question 12: *Are there other specific changes that could be made to reduce the burden imposed on researchers and their staffs in terms of meeting the requirements to submit documents to an IRB, without decreasing protections to subjects? Are there specific elements that can be appropriately eliminated from protocols or consent forms? Which other documents that are currently required to be submitted to IRBs can be shortened or perhaps appropriately eliminated? Conversely, are there specific additions to protocols or consent forms beyond those identified in this notice that would meaningfully add to the protection of subjects? What entity or organization should develop and disseminate such standardized document formats?*

There are several specific elements currently required by 46.116 that rarely pertain to surveys but commonly generate confusion among investigators when preparing consent documents for their surveys. Here, we list several elements that are largely irrelevant to most surveys. AASRO would encourage any revision that would specifically absolve surveys from the need to include the following two basic elements of informed consent: (a) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject, and (b) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained.

Question 13: *Given the problems with the current system regarding wide variations in the substance of IRB reviews, would it be appropriate to require IRBs to submit periodic reports to OHRP in the instances in which they choose to override the defaults described in Sections B(1), B(2)(a)(ii), and B(2)(b) above? Should IRBs have to report instances in which they require continuing review or convened IRB review of a study which involves only activities identified as being on the list of those eligible for Expedited review? If an IRB that chose to override these defaults was required to submit a report to OHRP, would this provide useful information about any lack of appropriate consistency among IRBs so that clarifying guidance could be provided as needed, or provide useful information to OHRP about the possible need to revise the Expedited review list or the continuing review requirements?*

AASRO takes the position that creating additional reporting requirements for IRBs will only serve to drain resources from their key function of protecting human subjects.

Moving Away from the Concept of Exempt

Question 14: *Are these expansions in the types of studies that would qualify for this Excused category appropriate? Would these changes be likely to discourage individuals from participating in research? Might these changes result in inappropriately reduced protections for research subjects, or diminished attention to the principles of respect for persons, beneficence, and justice?*

AASRO supports expansion of the types of studies that would qualify under the Exempt (or Excused) category. As this expansion of Exempt-eligible studies would be restricted to those involving competent adults, it is unlikely that this change would discourage many individuals from participating in research. It is also unlikely that this change to the Exemption classification would inappropriately reduce protections for research subjects, as competent adults will continue to be able to make their own informed decisions regarding the advantages and disadvantages of research participation.

Question 15: *Beyond the expansions under consideration, are there other types of research studies that should qualify for the Excused category? Are there specific types of studies that are being considered for inclusion in these expansions that should not be included because they should undergo prospective review for ethical or other reasons before a researcher is allowed to commence the research?*

AASRO believes that all survey research conducted with competent adults should qualify for the Excused category.

Question 16: *Should research involving surveys and related methodologies qualify for the Excused category only if they do not involve topics that are emotionally charged, such as sexual or physical abuse? If so, what entity should be responsible for determining whether a topic is or is not emotionally charged?*

AASRO believes that topics which are commonly understood to be highly sensitive, such as sexual and physical abuse, will unquestionably warrant careful consideration on a case-by-case basis by IRBs. We recommend, however, leaving it to the discretion of local institutional review boards to make decisions regarding which topics are sufficiently emotionally charged to warrant Expedited or Full review.

Question 17: *What specific social and behavioral research methodologies should fall within the Excused category? Under what circumstances, if any, should a study qualify for the Excused category if the study involves a form of deception (and if so, how should "deception" be defined)?*

Although this list is not exclusive, the methodologies generally understood and employed by AASRO's membership that we believe should be explicitly included within the Excused category include the following: surveys and interviews, regardless of data collection mode (e.g., interviewer administered via telephone, face-to-face, or via the internet, or self-administered via paper and pencil or internet), focus groups, and other social science methodologies that entail the direct collection of self-reported

information from competent adult human subjects. We also believe that the inclusion of auxiliary data that competent adults give informed consent to researchers to access and append to survey interviews should be included with the new Excused category. Regarding deception, which we define as *intentionally providing false or misleading information*, we do not believe that studies involving deception should be eligible for inclusion within the Excused category.

Question 19: *Regarding the Excused category, should there be a brief waiting period (e.g. one week) before a researcher may commence research after submitting the one page registration form, to allow institutions to look at the forms and determine if some studies should not be Excused?*

AASRO does not support the brief waiting period proposal in conjunction with the Excused category. Many surveys (which can be expected to fall into the Excused category) must be fielded on very short notice, sometimes within a matter of hours, in response to important public events. The waiting period requirement would pose a serious barrier to the conduct of valuable, rapid response research.

Question 20: *The term “Excused” may not be the ideal term to describe the studies that will come within the proposed revision of the current category of Exempt studies, given that these studies will be subject to some protections that are actually greater than those that currently exist. Might a term such as “Registered” better emphasize that these studies will in fact be subject to a variety of requirements designed to protect participants? We welcome other suggestions for alternative labels that might be more appropriate.*

AASRO takes no position on the term to be used to describe studies that will fall within the proposed revision of the current Exempt category. We note, however, that the term “Excused” implies that a determination has been made regarding the merits of the proposal, while “Registered” does not.

Question 21: *Is it appropriate to require institutions holding a Federal-wide Assurance to conduct retrospective audits of a percentage of the Excused studies to make sure they qualify for inclusion in this category? Should the regulations specify a necessary minimum percentage of studies to be audited in order to satisfy the regulatory requirements? Should some other method besides a random selection be used to determine which Excused studies would be audited?*

AASRO does not support the proposal to require that institutions holding a Federal-wide Assurance conduct retrospective audits of Excused studies to make determinations as to whether or not they were correctly qualified to be included in this category. AASRO strongly encourages the government to carefully pilot test such a requirement at a small number of volunteer institutions to determine feasibility in terms of time and cost burdens on the institution(s) required to perform the audit, relative to the fraction of incorrectly classified protocols that would likely be identified in such an audit.

Question 22: *Are retrospective audit mechanisms sufficient to provide adequate protections to subjects, as compared to having research undergo some type of review prior to a researcher receiving permission to begin a study? Might this new audit mechanism end up producing a greater burden than the current system? Do researchers possess the objectivity and expertise to make an initial assessment of whether their research qualifies for the Excused category? By allowing researchers to make their own determinations, without prospective independent review, will protections for some subjects be inappropriately weakened? If allowing researchers to make such determinations without independent review would generally be acceptable, are there nonetheless specific categories of studies included in the proposed expansion for which this change would inappropriately weaken protections for subjects? And will the use of a one-page registration form give institutions sufficient information to enable them to appropriately conduct the audits?*

AASRO notes that, in regards to retrospective audits, they will not serve to protect research subjects after the fact and should not be considered useful for that purpose. We also recognize that researchers may not always possess the objectivity and/or expertise necessary to correctly assess the risk levels associated with their research and the appropriate review category to which it should be assigned. We do not believe that the revisions to the Common Rule that are now being proposed have adequately resolved

the fundamental conflict between the need for the review process to avoid unnecessarily delaying minimal risk and time sensitive social research, and the importance of avoiding situations in which well-intentioned but naïve researchers underestimate the risks associated with their research. This is a very important problem that should receive more careful thought and consideration before any new rules are implemented.

Question 23: *Under what circumstances should it be permissible to waive consent for research involving the collection and study of existing data and biospecimens as described in Section 3(a)(3) above? Should the rules for waiving consent be different if the information or biospecimens were originally collected for research purposes or non-research purposes? Should a request to waive informed consent trigger a requirement for IRB review?*

AASRO takes the position that as long as the definition of “existing” data and biospecimens is clarified as described in Section 3(a)(3), it should be permissible to waive consent to use these data for other research purposes when the data are de-identified and cannot be re-identified. If the data can be re-identified, the IRB would then need to review the request for a waiver of consent.

As to whether there should be different rules for waiving consent for data originally collected for research purposes versus non-research purposes, AASRO takes the position that this distinction is unnecessary. Indeed, the proposed consent requirements in Table 1 suggest that there should be more constraints on the future use of pre-existing data obtained for research than non-research purposes. Consent for future research would be needed for data collected for research purposes but not necessary for de-identified data collected for non-research purposes. AASRO believes that in the former case, since consent was obtained for one research purpose, whereas in the latter case consent was never obtained for any research purpose, if there were to be differential standards it would make more sense for those who were never consented to be provided the stronger privacy protections.

Question 24: *The Common Rule has been criticized for inappropriately being applied to—and inhibiting research in-- certain activities, including quality improvement, public health activities, and program evaluation studies.^{50 51 52} Regarding quality improvement, for example, these activities are in many instances conducted by health care and other organizations under clear legal authority to change internal operating procedures to increase safety or otherwise improve performance, often without the consent of staff or clients, followed by monitoring or evaluation of the effects. It is far from clear that the Common Rule was intended to apply to such activities, nor that applying it produces any meaningful benefits to the public. Indeed, its application to such activities, and requiring IRB review and compliance with informed consent requirements, might have a chilling effect on the ability to learn from, and conduct, important types of innovation. We seek comment on whether and, if so, how, the Common Rule should be changed to clarify whether or not oversight of quality improvement, program evaluation studies, or public health activities are covered. Are there specific types of these studies for which the existing rules (even after the changes proposed in this Notice) are inappropriate? If so, should this problem be addressed through modifications to the Exemption (Excused) categories, or by changing the definition of “research” used in the Common Rule to exclude some of these studies, or a combination of both? And if the definition of research were to be changed, how should the activities to be excluded be defined (e.g., “quality improvement” or “program evaluation”)? Are there some such activities that should not be excluded from being subject to the Common Rule because the protections provided by that rule are appropriate and no similar protections are provided by other regulations? With regard to quality improvement activities, might it be useful to adopt the distinction made by the HIPAA Privacy Rule (45 CFR 164.501(1)), which distinguishes between “health care operations” and “research” activities, defining “health care operations” to include “conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities”?*

AASRO fully supports the notion that the Common Rule should be clarified to exclude from its purview responsibility for oversight of program evaluation, quality improvement, and public health surveillance activities, to the extent that the primary purpose of these activities is not research (i.e., the development

of generalizable knowledge). We note, for example, the distinction between surveys conducted for surveillance, in which the benefits of conducting the survey are realized by the participants surveyed, in contrast to surveys conducted strictly for research, in which the benefits of conducting the survey are realized by some group other than the participants surveyed. AASRO recommends that the definition of research be modified to provide examples of “non-research” that include examples of survey activities in which the benefits are primarily designed to accrue to the participating community, regardless of survey topic.

Question 25: *Are there certain fields of study whose usual methods of inquiry were not intended to or should not be covered by the Common Rule (such as classics, history, languages, literature, and journalism) because they do not create generalizable knowledge and may be more appropriately covered by ethical codes that differ from the ethical principles embodied in the Common Rule? If so, what are those fields, and how should those methods of inquiry be identified? Should the Common Rule be revised to explicitly state that those activities are not subject to its requirements?*

AASRO support the proposal to revise the Common Rule to specifically exclude the common methods and practices of academic fields that do not typically seek, as their primary goal, to produce generalizable knowledge through interaction with human subjects (as currently defined in the Common Rule). These fields might include art, cultural anthropology, English, history, journalism, languages, literature, music, theater, and others.

Question 26: *The current Exempt category 5 applies to certain research and demonstration projects that are designed to study or evaluate public benefit or service programs. Is the circumstance that a particular demonstration project generates “broad” knowledge incorrectly being used as a reason to prevent certain activities (including section 1115 waivers under Medicaid) from qualifying for Exempt category 5? If so, how should this exemption (as part of the new category of Excused research) best be revised to assure that it will no longer be misinterpreted or misapplied? Would broadening the interpretation of the exemption result in inappropriately increased risks to participants in research? If so, how could such risks be mitigated? Also, is there a need to update or otherwise revise the “OPRR Guidance on 45 CFR 46.101(b)(5)”?*

AASRO believes research currently exempted under Category 5 should continue to receive that exemption and that the current waiver should be revised to clearly indicate that federal research and demonstration projects are exempted, even if such studies are sufficiently well-designed to have the potential to produce generalizable knowledge. We believe that research should not be held to a higher standard for the sole reason that it is sufficiently well-designed to warrant peer-reviewed publication.

Question 27: *The Common Rule currently states (45 CFR 46.111(a)(2)) that an IRB “should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among the research risks that fall within the purview of its responsibility.” Do IRBs correctly interpret this provision as meaning that while they should be evaluating risks to the individual subjects participating in a study, it is not part of their mandate to evaluate policy issues such as how groups of persons or institutions, for example, might object to conducting a study because the possible results of the study might be disagreeable to them? If that is not how the provision is typically interpreted, is there a need to clarify its meaning?*

AASRO believes strongly that IRBs are correct when interpreting the Common Rule as a mandate to consider a proposed study’s potential risks to individual participating subjects, and should not consider policy issues regarding how social groups or institutions might object to the conduct of a study that might be relevant to their undefined interests. Any clarification on this important point that can be introduced is encouraged. In relation to this, we disagree with the statement made on p. 44516 of the Federal Register (Vol .27, No. 143 / Tuesday, July 26, 2011 / Proposed Rules; column 1, lines 3-6) that “Informational risks derive from inappropriate use or disclosure of information, which could be harmful to the study subjects or groups (emphasis added).” We believe that opening the door to invite social - and inevitably, political interest - groups to object to the conduct of scientific research (on the grounds that potential findings

might hypothetically be detrimental to the interests of any group) would be a serious mistake that could unnecessarily politicize the ethical review of human subjects research and subvert the original goal of protecting individuals from any risks associated with research participation.

Question 28: *For research that requires IRB approval, the Common Rule does not currently require that the researcher always be allowed some form of appeal of a decision (e.g., disapproval of a project). Some institutions have voluntarily chosen to provide appeal mechanisms in some instances, by, for example, allowing the researcher to present the project to a different IRB, or by having it reviewed by a special “appeal” IRB that is composed of members chosen from among the membership of the institution’s other IRBs. Should the Common Rule include a requirement that every institution must provide an appropriate appeal mechanism? If so, what should be considered acceptable appeal mechanisms? Should such appeal mechanisms, or different ones, be available for appeals asserting that the investigation is not research, or that the research does not require IRB approval?*

AASRO agrees that a decision appeal mechanism should be required at all institutions, in order to remove from IRBs the burdensome accusation that they are omnipotent. We believe that a variety of potential appeal mechanisms should be considered, including external appeal to a different IRB, and take no position on which approach would be preferred or optimal.

Question 29: *As noted above, IRBs sometimes engage in activities beyond those that are required by the regulations. For example, an IRB might review some studies for the purpose of determining whether or not they qualify for exemption (the new Excused category), or might review studies involving the analysis of data that is publicly available. Would it be helpful, in furtherance of increased transparency, to require that each time an IRB takes such an action, it must specifically identify that activity as one that is not required by the regulations?*

AASRO does not support the practice of IRBs engaging in activities beyond those specifically required by the regulations and recommends that the revised regulations specifically prohibit IRBs from assuming responsibilities and authorities that they have not been formally charged with performing.

II) Streamlining IRB Review of Multi-Site Studies

AASRO appreciates the challenge of insuring adequate oversight of multi-site research. While we agree that steps should be taken to increase efficiency and reduce delays in the IRB review process for multi-site studies, we are concerned about lack of local knowledge of the investigators and their study personnel, lack of institutional control over whether they should be involved in the research in question, and the lack of assurance that the single IRB of record is competent. Since some of the delay in reviewing these protocols is due to institutions’ differential cultures and requirements regarding consent form wording to protect the institutions (as opposed to the research participants), if the reforms discussed below for limiting what can and should go into a consent form are adopted, this may greatly help investigators get a timely review.

Question 30: *What are the advantages and disadvantages of mandating, as opposed to simply encouraging, one IRB of record for domestic multi-site research studies?*

AASRO takes the position that the biggest advantages could be the avoidance of long delays for the investigators due to institutions’ differential cultures, requirements and timelines for approving research activities and consent form protections. The biggest disadvantages are that it would remove local knowledge from the process and depending on what model is adopted to determine the IRB of record (government, private, rotating research institution), it could simply be replacing one bureaucratic process with another that does not improve protections to research subjects, and could increase potential harms to participants if the IRB is not of high quality. This remains a difficult issue that requires further review and consideration, as many institutions will likely decline to accept legal liability, and hence prohibit their investigators to participate, without local review and approval.

Question 31: *How does local IRB review of research add to the protection of human subjects in multi-site research studies? How would mandating one IRB of record impair consideration of valuable local knowledge that enhances protection of human subjects? Should the public be concerned that a centralized IRB may not have adequate knowledge of an institution's specific perspective or the needs of their population, or that a centralized IRB may not share an institution's views or interpretations on certain ethical issues?*

AASRO notes that local IRBs have important knowledge not only of the investigators and the qualifications of their research staff, but also of the proposed local population.

Question 33: *How significant are the inefficiencies created by local IRB review of multi-site studies?*

AASRO believes these inefficiencies are significant and lead to long delays for investigators which can put the research at risk due to funding agency time-lines. As noted above, if a move were made to standardize and shorten consent forms and to limit the content that does not protect the participants' rights, much of the problem would be addressed without moving away from local IRB review.

Question 34: *If there were only one IRB of record for multi-site studies, how should the IRB of record be selected? How could inappropriate forms of "IRB shopping"—intentionally selecting an IRB that is likely to approve the study without proper scrutiny—be prevented?*

AASRO recognizes that there may be unscrupulous investigators that would attempt to take advantage of this, but in general believes that this scenario is unlikely. AASRO believes that the vast majority of investigators have the best interests of the research participant in mind. If the single IRB model is adopted, it should not be a single institutions' IRB, but a central IRB that has been accredited, whether through AAHRPP or some other federal oversight process.

III) Improving Informed Consent

Improving Consent Forms

AASRO recognizes the importance of consent documents in protecting the ethical and legal rights of research participants and supports any effort to make these forms shorter and more useful with a standard format free of institutional boilerplate and clearer presentation of the key study information in language understandable to a wide range of study participants.

Question 35: *What factors contribute to the excessive length and complexity of informed consent forms, and how might they be addressed?*

Current consent forms are often repetitive and sometimes overloaded with institutional language requirements that appear to be designed to provide legal protections for the institution rather than ethical protections for the research participant. This excessive legalese often becomes the most burdensome aspect of participating in a simple survey. Reducing a written form to 3 or 4 key informational points will both improve the participant's understanding and potentially increase study participation. Using a Question-and-Answer format may be preferable to the current text format for most modes of survey administration.

Question 36: *What additional information, if any, should be required by the regulations to assure that consent forms appropriately describe to subjects, in concise and clear language, alternatives to participating in the research study and why it may or may not be in their best interests to participate? What modifications or deletions to the required elements would be appropriate?*

Consideration should be given for different consent form templates for different types of research studies. For many social and behavioral research studies, the only alternative to participation is not participating.

There is no other drug or treatment to take; these participants are allowing their lives to be observed so that societal knowledge can be gained. For them, stressing alternatives is misleading.

Question 37: *Would the contemplated modifications improve the quality of consent forms? If not, what changes would do so?*

AASRO supports the overall tone of the contemplated modifications.

Question 38: *Should the regulations require that, for certain types of studies, investigators assess how well potential research subjects comprehend the information provided to them before they are allowed to sign the consent form?*

AASRO takes the position that anytime there is a clearly foreseeable physical or psychological risk involved with study participation the regulations should require that questions be asked prior to accepting consent to ensure complete understanding of study participation and its associated risks and benefits. This should also be required anytime a participant's level of comprehension due to age, disease, language skill or education is questionable. In many cases readily available cognitive functioning tests would suffice.

Question 39: *If changes are made to the informed consent requirements of the Common Rule, would any conforming changes need to be made to the authorization requirements of the HIPAA Privacy Rule?*

AASRO recommends that these two documents be written in similar fashion, and combined into one, whenever possible, for ease of the participant. We do not recommend, however, merely extending HIPAA regulations to research covered by the Common Rule, as HIPAA's exclusive emphasis on medical research may in some cases introduce inappropriate requirements when applied to the broader research community.

Question 40: *Would informed consent be improved if the regulations included additional requirements regarding the consent process, and if so, what should be required? For example, should investigators be required to disclose in consent forms certain information about the financial relationships they have with study sponsors?*

In principle, AASRO believes that any factor that could influence a participant's decision about study participation should be disclosed. These could include the study sponsors, the investigators' relationships with study sponsors, recruiting institutions, production companies that could benefit from study results, etc. If study results (from a blood test for example) cannot be provided back to the participant, the rationale for this should be clearly explained.

Waiver of Informed Consent or Documentation of Informed Consent in Primary Data Collection

Question 41: *What changes to the regulations would clarify the current four criteria for waiver of informed consent and facilitate their consistent application?*

AASRO believes that if the "practicability" criterion is retained, the modified regulations emphasize that "practicability" refers to the practicability of the research if the waiver is not granted, and not solely to the practicability of obtaining consent.

Question 42: *In circumstances where the regulations would permit oral consent, what information should investigators be required to provide to prospective subjects? Are all of the elements of informed consent included at 45 CFR 46.116 necessary to be conveyed, or are some elements unnecessary? If some elements should not be required for oral consent, which ones are unnecessary?*

It is AASRO's position that for minimal risk studies like those typically undertaken by survey researchers, required information to be provided orally should include the following: 1) an explanation of the purposes and requirements of the survey and that participation is voluntary; 2) how the participant was selected; 3) a description of the procedures and the expected duration of the subject's participation, both in terms of

length of interview and duration of study overall; 4) what will be done with the information that was collected; and 5) that confidentiality of records identifying the subject will be maintained.

Unnecessary elements of oral consent in the context of minimal risk survey studies include: 1) identification of any procedures which are considered experimental; 2) a description of any reasonably foreseeable risks or discomforts to the subject; 3) a description of any benefits to the subject or to others which may be reasonably be expected from the research; 4) a description of “loss of benefits” when there are no direct benefits of participation to the respondent; and 5) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

Question 43: *Are there additional circumstances under which it should be permissible to waive the usual requirements for obtaining or documenting informed consent?*

AASRO believes the circumstances for waiving documentation should be broadened to include the risk of the consent requirement introducing bias into the overall study with little proven protection to the subject. For example, in instances where oral consent is viable or appropriate, requiring written consent may lead some to not participate merely because they are concerned about signing forms or are burdened by having to do so. There is also cultural variability in terms of willingness to sign consent forms that should be recognized and respected. Finally, institutions should be required to have a formal process and associated forms for requesting a waiver of informed consent, particularly written informed consent.

Question 44: *Are there types of research involving surveys, focus groups, or other similar procedures in which oral consent without documentation should not be permitted? What principles or criteria distinguish these cases?*

AASRO believes that oral consent should not be allowed in survey studies that include collection of biospecimen data. First, much of those data (viz. DNA) cannot be fully de-identified due to the nature of the information. Second, because funding agencies are increasingly requiring that biospecimen data be posted on common sites for public availability, prospective participants should know that the information they provide might not just reside at the sponsoring institution. Third, there may be incidental findings that emerge through certain types of biospecimen data that the participant may not fully comprehend if the consent is administered and secured orally. For example, genomic/exomic studies oftentimes come across genetic risk information (e.g., carrier for the Parkinson’s gene) that may be of interest to the participant but the participant did not fully realize it could be ascertained. This possibility should be presented thoroughly to the participant in both oral and written forms.

Finally, and potentially most importantly, in the context of a typical social survey, prospective participants are not used to being asked for biospecimen data, only typical questions and provision of answers. Given that survey-based biospecimen collection is a recent phenomenon where the typical U.S. resident is not familiar with what that might entail and all the associated risks – coupled with the lack of agreed-upon best practices in this space – erring on the side of caution requires that consent be administered and secured via both written and oral methods in this context.

Strengthening Consent Protections Related to Reuse or Additional Analysis of Existing Data and Biospecimens

Question 45: *Under what circumstances should future research use of data initially collected for non-research purposes require informed consent? Should consent requirements vary based on the likelihood of identifying a research subject? Are there other circumstances in which it should not be necessary to obtain additional consent for the research use of currently available data that were collected for a purpose other than the currently proposed research?*

As AASRO members are overwhelmingly concerned with the collection of research data to be used for statistical purposes, and not “non-research” (or “administrative”) data, we do not take a position on informed consent practices in the collection of original non-research data.

While the first and second parts of this question are also asked specifically for research data in Question 46 and are addressed there, the third sub-question, “Are there other circumstances in which it should not be necessary to obtain additional consent for the research use of currently available data that were collected for a purpose other than the currently proposed research?” can apply to currently available research data as well. We believe that the future, secondary use of research data for different research purposes should be permitted without additional consent when a) the future use would result in a level of risk that does not exceed that of the original research program, and b) the data security protections against disclosure equal or exceed those of the original research program. In these circumstances, it should not be necessary to obtain (additional) consent.

Question 46: *Under what circumstances should unanticipated future analysis of data that were collected for a different research purpose be permitted without consent? Should consent requirements vary based on the likelihood of identifying a research subject?*

As in Question 45, future use of research data for different research purposes should be permitted without additional consent when a) the unanticipated use would result in a level of risk that does not exceed that of the original research program, and b) the data security protections against disclosure equal or exceed those of the original research program. However, AASRO suggests that, for minimal risk surveys with competent adults, during the original consent process that research participants be asked for permission to use their data for unanticipated future analysis of the data as long as the data remain confidential to the fullest extent promised in the original research.

Also, the Common Rule allowance in “certain situations” of a “general consent” at the time of the original research program to unspecified future research with that identifiable data should be extended more broadly to cover any research of minimal risk and the required data security protections.

However, if linkage to participant-specific information which was not part of the original research is proposed as part of the unanticipated future analysis, the researcher must evaluate whether or not the inclusion of those additional data in the original research request would have resulted in an increase in risk above the minimal level, and subsequently higher consent requirements, and if so, those additional requirements must be met before the linkage and analysis are performed. The researcher should also consider whether research subjects might reasonably have been less inclined to participate if they had also been presented with those data items which would later be linked to and analyzed with the original data items they were aware of at the time they made their decision to participate.

Finally, consent requirements should vary based on the likelihood of identification of the research subject (for example, due to the addition of participant-specific information), when a) the risk exceeds minimal levels or b) the level of data security protections would not be raised to a commensurate level. Also, for research data that are already in an identifiable form, linkage to additional identifiers, as long as they do not cause linkage-related reconsideration of the original consent procedure, does not constitute a reason in itself that consent requirements should be increased.

Question 47: *Should there be a change to the current practice of allowing research on biospecimens that have been collected outside of a research study (i.e. “left-over” tissue following surgery) without consent, as long as the subject’s identity is never disclosed to the investigator?*

To the extent this question strictly concerns biospecimens collected outside of a research study, and not research data per se, AASRO does not take a position. [AASRO recommends consistently separate treatment of social science research data from biospecimens.]

Question 48: *What, if any, are the circumstances in which it would be appropriate to waive the requirement to obtain consent for additional analysis of biospecimens?*

AASRO takes the position that there should be no additional circumstances.

Question 49: *Is it desirable to implement the use of a standardized, general consent form to permit future research on biospecimens and data? Are there other options that should be considered, such as a public education campaign combined with a notification and opt-out process?*

AASRO believes that while a standardized, general consent form – if greatly simplified – would improve the informed consent process, waiver of informed consent for minimal risk social science research data should be more broadly applied as discussed earlier.

Question 50: *What is the best method for providing individuals with a meaningful opportunity to choose not to consent to certain types of future research that might pose particular concerns for substantial numbers of research subjects beyond those presented by the usual research involving biospecimens? How should the consent categories that might be contained in the standardized consent form be defined (e.g. an option to say yes-or-no to future research in general, as well as a more specific option to say yes-or-no to certain specified types of research)? Should individuals have the option of identifying their own categories of research that they would either permit or disallow?*

AASRO believes that for social science research programs of elevated risk, particularly in health research, when informed consent is not waived, a “general consent” approach allowing unspecified future use for any research and commercial purposes should be taken (see response to Question 46 above). Given the practical difficulties of communicating choices and acting upon them in the future, a simple and broad “yes-or-no” directive should be obtained from the participant.

Question 51: *If the requirement to obtain consent for all research uses of biospecimens is implemented, how should it be applied to biospecimens that are collected outside of the U.S. but are to be used in research supported by a Common Rule agency? Should there be different rules for that setting, and if so, what should they be? Should they be based on the relevant requirements in the countries where the biospecimens were collected?*

AASRO believes that to the extent this question includes research data as well as biospecimens, the rules and regulations, if any, that the controlling body governing the original data provider imposed on the use and management of the original data should determine Common Rule agency treatment of it as secondary data. Therefore, even in the event that consent for secondary use of data were to be adopted broadly in the U.S., if study data were obtained on research subjects from a research provider outside of the U.S., and this provider was originally held to a lower level of consent requirement, that lower level would prevail.

Question 52: *Should the new consent rules be applied only prospectively, that is, should previously existing biospecimens and data sets be “grandfathered” under the prior regulatory requirements? If so, what are the operational issues with doing so?*

AASRO endorses the concept of “grandfathering” in this case, and suggests the most commonly agreed-upon dating requirements for determining the operational date to apply to each research program and the date for rule change implementation to compare it against.

Question 53: *In cases in which consent for future research use is not obtained at the time of collection, should there be a presumption that obtaining consent for the secondary analysis of existing biospecimens or identifiable data would be deemed impracticable, such that consent could be waived, when more than a specified threshold number of individuals are involved? (SACHRP provided the Secretary with recommendations on this issue.⁸¹) If so, what threshold number should constitute impracticability? Is the number of potential human subjects the only measure of impracticability?*

While we maintain that almost all social science research data should be exempt from the requirements, AASRO endorses the SACHRP recommendations on 45 CFR 46.116(d), taking into account our position on the definition of minimal risk. Also, we believe that in cases of minimal risk, appropriate data security requirements would mitigate the risk from re-identifying previously unidentifiable data because of data linkage (and thus would not typically be a consideration for IRBs in deciding whether to waive the requirement).

Like SACHRP, we believe that threshold values for numbers of subjects involved, the nature of impracticability due to the passage of time or the researcher's resources, and the impact on subjects to be contacted as part of obtaining consent be determined by IRBs on a study-by-study basis.

IV) Strengthening Data Protections to Minimize Information Risks

AASRO endorses the effort to strengthen data security to minimize the risk of breach of confidentiality. AASRO also endorses efforts to eliminate the need for IRBs to evaluate data security and information protections. However, we do not believe the full HIPAA model is appropriate for most minimal risk social and behavioral research, particularly with respect to the HIPAA standards for what constitutes identifiable data and its notification requirements in the event of a security breach.

Consistently Characterizing Information with respect to Potential for Identification

Question 54: *Will use of the HIPAA Privacy Rule's standards for identifiable and de-identified information, and limited data sets, facilitate the implementation of the data security and information protection provisions being considered? Are the HIPAA standards, which were designed for dealing with health information, appropriate for use in all types of research studies, including social and behavioral research? If the HIPAA standards are not appropriate for all studies, what standards would be more appropriate?*

AASRO takes the position that the strict application of HIPAA standards is not appropriate for most minimal risk social and behavioral research studies. In particular, requiring that sub-state geographic indicators such as zip code and county must be removed to consider datasets de-identified is unnecessary for most survey research. While it is possible that using these variables in combination with other demographics may allow re-identification in a small number of cases, this is not typical of large social science datasets. Applying the HIPAA standards for de-identified datasets would also have a chilling effect on researchers contributing their data to long-standing data archives that are extremely valuable to social and behavioral scientists. For the vast majority of research studies, including these variables would not increase the likelihood of identifying respondents. We believe that the HIPAA standards may be appropriate for a limited number of studies where these sub-state indicators could be used to re-identify data, but a lesser standard would be appropriate for most social and behavioral research.

Furthermore, the HIPAA notification standards are inappropriate for minimal risk social and behavioral research and would place undue burden on the researcher. While the AASRO's Code of Ethics emphasizes that keeping all identifying information confidential is an ethical obligation unless confidentiality is explicitly waived by the participant, for most minimal risk studies (where the biggest risk is breach of confidentiality), even a breach of confidentiality would not place research participants at risk in most circumstances. Ethically, we believe that our promise to the respondent regarding confidentiality is inviolate, but that in most social and behavioral research those promises can be kept without resorting to the full HIPAA standard.

Question 55: *What mechanism should be used to regularly evaluate and to recommend updates to what is considered de-identified information? Beyond the mere passage of time, should certain types of triggering events such as evolutions in technology or the development of new security risks also be used to demonstrate that it is appropriate to reevaluate what constitutes de-identified information?*

AASRO agrees that technological innovations could make it easier to re-identify data in the future, but we wonder how those triggering events should be defined. We agree that whatever standards are adopted to define de-identified data, this definition should be revisited periodically, but not more frequently than every three to five years so as to not present the research community with constantly shifting standards.

Standards for Data Security and Information Protection

Question 58: *Should the new data security and information protection standards apply not just prospectively to data and biospecimens that are collected after the implementation of new rules, but instead to all data and biospecimens? Would the administrative burden of applying the rule to all data and biospecimens be substantially greater than applying it only prospectively to newly collected information and biospecimens? How should the new standards be enforced?*

AASRO believes that any new data security and information standards should only be applied prospectively. The administrative burden on researchers to retrospectively apply the standards would be too great. Retrospective application of the standards will most likely hinder ongoing longitudinal research studies and surveys and limit the usefulness of data currently deposited in large archives such as the Interuniversity Consortium for Political and Social Research (ICPSR), the Roper Center, or the Odum Institute.

Question 59: *Would study subjects be sufficiently protected from informational risks if investigators are required to adhere to a strict set of data security and information protection standards modeled on the HIPAA Rules? Are such standards appropriate not just for studies involving health information, but for all types of studies, including social and behavioral research? Or might a better system employ different standards for different types of research? (We note that the HIPAA Rules would allow subjects to authorize researchers to disclose the subjects' identities, in circumstances where investigators wish to publicly recognize their subjects in published reports, and the subjects appreciate that recognition.)*

AASRO supports the idea of having different standards for different types of research. We believe that while some minimal standards should apply to all research, such as the requirement that data be encrypted, minimal risk social and behavioral research does not require the informational risk protections that other types of research (such as clinical trials) may require. In particular applying the HIPAA model to minimal risk surveys will unnecessarily prohibit many studies while providing no additional increase in protection to research participants and hinders valuable social research.

Question 60: *Is there a need for additional standardized data security and information protection requirements that would apply to the phase of research that involves data gathering through an interaction or intervention with an individual (e.g. during the administration of a survey)?*

AASRO recognizes that the point of a research project where the risk of a breach of confidentiality is greatest is during the interaction where data are collected. For example, when using the web as a mode of survey data collection, the window of greatest vulnerability for the data is during the time the application is open and being used by the participant and during the transmission of the data to its home file server. For these reasons AASRO recommends that any new standards encourage data encryption on all electronic data storage devices, including flash drives and laptops. Furthermore, AASRO recommends that research personnel who directly collect or handle data be required to sign non-disclosure agreements.

Question 61: *Are there additional data security and information protection standards that should be considered? Should such mandatory standards be modeled on those used by the Federal government (for instance, the National Institute of Standards and Technology recently issued a "Guide to Protecting the Confidentiality of Personally Identifiable Information.")?*

AASRO recommends that additional standards such as those used by the federal government should not be mandatory. However, we support a minimum standard and endorse the idea that if a higher level of protection is available to a researcher, its use should be encouraged.

Question 62: *If investigators are subject to data security and information protection requirements modeled on the HIPAA Rules, is it then acceptable for HIPAA covered entities to disclose limited data sets to investigators for research purposes without obtaining data use agreements?*

If standards are modeled on HIPAA rules, AASRO takes the position that data use agreements should not be required for social and behavioral limited use datasets.

Question 63: *Given the concerns raised by some that even with the removal of the 18 HIPAA identifiers, re-identification of de-identified datasets is possible, should there be an absolute prohibition against re-identifying de-identified data?*

AASRO notes that there are instances where it is appropriate for the investigator who collected the data and de-identified it to re-identify data for analytic checks and data quality control purposes. However there should be an absolute prohibition on sharing re-identified data with other researchers.

Question 64: *For research involving de-identified data, is the proposed prohibition against a researcher re-identifying such data a sufficient protection, or should there in some instances be requirements preventing the researcher from disclosing the de-identified data to, for example, third parties who might not be subject to these rules?*

AASRO strongly endorses the idea that de-identified data should not be shared with third parties not subject to the rules proposed in this ANPRM if there is a reasonable possibility that the data be re-identified. However, we note that individual members of AASRO institutions subscribe to high ethical standards that would prevent us from sharing data that could be re-identified with third parties not subject to the rules.

Question 65: *Should registration with the institution be required for analysis of de-identified datasets, as was proposed in Section II(B)(3) for Excused research, so as to permit auditing for unauthorized re-identification?*

AASRO takes the position that registration should not be required. This places an undue burden on researchers using publicly available de-identified research datasets which have no reasonably foreseeable way of being re-identified.

Question 66: *What entity or entities at an institution conducting research should be given the oversight authority to conduct the audits, and to make sure that these standards with regard to data security are being complied with? Should an institution have flexibility to determine which entity or entities will have this oversight responsibility for their institution?*

In the interest of local control and input, AASRO believes that institutions should have flexibility to determine which entities will conduct the audits. However, we strongly recommend that those entities have among their membership, information technology personnel and individuals with statistical expertise.

V) Data Collection to Enhance System Oversight

AASRO takes no position on this issue.

VI) Extension of Federal Regulations

71: *Should the applicability of the Common Rule be extended to all research that is not Federally funded that is being conducted at a domestic institution that receives some Federal funding for research with human subjects from a Common Rule agency?*

AASRO takes the position that all such research should be covered by the Common Rule to ensure that there is equal, adequate and consistent protection for human research subjects.

VII) Clarifying and Harmonizing Regulatory Requirements and Agency Guidance

AASRO generally endorses the idea that steps should be taken to make requirements and guidance more consistent across agencies, but we recognize that different types of research (e.g., social and behavioral research versus clinical trials) will require different regulatory requirements.