January 6, 2016

Jerry Menikoff, M.D., J.D.
Office for Human Research Protections (OHRP)
Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852


Dear Dr. Menikoff,

We are writing on behalf of the American Educational Research Association (AERA), the Interuniversity Consortium for Political and Social Research (ICPSR), the Consortium of Social Science Associations (COSSA), the Council of Professional Associations on Federal Statistics (COPAFS), and the many individual members, organizations, and institutions that we serve. We appreciate the opportunity to comment on the Notice of Proposed Rulemaking for the Federal Policy for the Protection of Human Subjects1 for the Common Rule (45CFR46, Subpart A). We commend the thoughtful process that has gone into this Notice, starting with the Advanced Notice for Proposed Rulemaking (ANPRM) issued in July 2011, the consideration of comments offered by relevant stakeholders in response to that Notice, the attention to the National Research Council’s 2014 Report addressed to the Proposed Revisions to the Common Rule,2 and the extensive interagency effort that went into proposing these revisions. We share the view that regulations promulgated in 1974, revised in 1981, and issued with only modest changes in 1991 required modernization, simplification, and enhancement in order to align ethically responsible conduct with research participants and progress in the human sciences that is of benefit to all.

We commend the consideration of the three guiding principles of the 1979 Belmont Report3—beneficence, respect for persons, justice—in undertaking the proposed revisions. We support the underlying objective of recalibrating the human research protection system so that Institutional Review Boards (IRBs) focus their efforts on research that poses more than minimal risk of harm. The attention to the classification of research as excluded, exempt, or appropriate for expedited review; to publically available information; to the treatment of research and non-research information; to mechanisms of data protection and security; to the protection of personal private information; and to consent is welcomed. Overall, the NPRM offers improvements to a human research protection system that is long overdue for change.

1 We support the use of the term “research participants” rather than “human subjects” and urge that this language change be made in issuing revised regulations.
Our comments set forth herein are directed to some of the key issues and questions most relevant to the social and behavioral sciences. Although, as we will point out, there are areas where the proposed rule changes still require considerable work in their detail, there are major and substantial improvements that should not be delayed or deferred even if it is determined that some issues require further analysis before some rule changes can be made (e.g., one such issue might be the definition of human subjects to include biospecimens or consent for all biospecimen research irrespective of identifiability). This letter briefly overviews areas of very positive proposed regulatory change and also notes areas where some clarifications could enhance the proposed revision to the Common Rule.

Overview of Major Improvements

We appreciate the attention in the revision as set forth in the NPRM to addressing social and behavioral science research perspectives.

- We support the proposed revision of 46.101 (“To What does this policy apply”) with respect to research excluded from consideration under the policy. We support the exclusion of research that does not meet the definition of human subjects research for purposes of this policy (46.101[b][1]) and also the further exclusion of research that is low risk and where there are independent controls in place 946.101[b][2]. These exclusions would importantly include public information and surveys, educational tests, interview procedures, or observations (uninfluenced by the investigator) that are recorded without identifiers or would not reasonably place persons at risk of legal liability or personal damage. We commend excluding research on children that only involves educational tests or “observations of public behavior when the investigator does not participate in the activities being observed,” although we encourage a harmonization of the Common Rule with Subpart D Related to Children Involved as Subjects. Also, we note the logic of excluding oral history methods when the research is “focused directly on the specific individuals about whom the information is collected” and ethical standards of practice are quite well specified.

- We in particular appreciate the rethinking of exempt research in terms of (1) what is included, and (2) how it is handled. The proposed revision to the Common Rule offers a well-reasoned approach that is respectful of human subjects and consonant with adhering to the Belmont principles for low-risk research. We have already noted above the judicious differentiation between excluded and exempt research and are pleased that the essential recommendations set forth in the 2014 NRC helped to inform the treatment of exempt research, as set forth in 46.104. We are very pleased with the specification of new exempt categories at 46.104(d)(3)(i) for research involving benign interventions with adults; at 46.104(e)(1) for research including educational tests, surveys, interview procedures, and the like that is identifiable as long as the standards for data protection are in place; at 46.104(e)(2) for secondary research use of private non-research information acquired for research purposes under specific conditions of prior notice and use; and at 46.104(f)(1) for

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4 The Council of Government Relations in its letter of December 8, 2015, the Association of American Universities and the Association of Public and Land-grant Universities in their joint letter of December 22, 2015, independent comments offered by higher education institutions such as Stanford University (letter of November 18, 2015) raise issues related to biospecimens that merit further consideration in weighing the regulatory rule changes.
the storage, maintenance, and use of private, identifiable information for future research studies under specified conditions. We support the proposal to allow exempt research to include “sensitive information” as specified in 46.104(e) as long as standards for the Protection of Private Identifiable Information (46.105) and the general conditions for all exempt research set forth in 46.104(c) are met (i.e., the investigator made a determination that the research is exempt following the mandated “decision tool” and institutional or IRB records are maintained).

- We also note the continuation in the proposed revisions of the exemption for research in educational settings that involves normal educational practices (46.104[d][1]). We support the continuation of this exemption as allowing for important research respectful of research participants without burden to the human research protection system. Also, we appreciate the explicit attention in 46.104(b)(3) to Subpart D Related to Children. This section notes that the exemptions set forth in 46.104(d)(1) on normal education practices in education settings, in (e)(2) on research use of non-research information, and (f)(1) on storage, maintenance, and subsequent use of research data, among others, can be conducted under Subpart D if the conditions for the exemption are met.

- We appreciate the commitment to developing a robust decision tool that can enable investigators to make wise and accurate determinations of informed consent. It would be wise to introduce common elements rather than to allow for wide variation in what the tool includes and how it functions. While such a tool needs to be developed and vetted with expert advice and diverse stakeholder input, it should be feasible to have a product that serves the function of allowing for appropriate investigator decisionmaking and recordkeeping. The 2014 NRC Report included at page 56 a Draft Model for An Excused Research Registration Form (using the language of the ANPRM). It captures important elements of record keeping.

- We were pleased that the proposed changes to the Common Rule as set forth in the NPRM no longer privilege HIPAA privacy standards. We see the revisions as allowing for strengthened privacy and security guidelines. As a newly proposed section within the Common Rule—46.105—it itself sends an important signal about responsibilities to research participants and the importance of sound practices for protection confidentiality and data security. It also stipulates in the Safeguards requirements ([46.105[b]]) that requirements should be evaluated “at least every 8 years.” Because of the fast-pace changes in technology that need to be considered, 8 years may be too lengthy a period, but the importance of seeing the standards as requiring periodic review is to be commended.

- We appreciate the awareness in the NPRM that HIPAA is not appropriate for much of social and behavioral science research. As a privacy act, it is in general not well suited as a vehicle to secure the confidentiality of identifiable information and ensure data protection and security. We understand that safeguards have not yet been specified. Like the decision tool for exempt research, they remain to be developed. Nevertheless, the commentary accompanying the proposed revisions to the Common Rule shows an awareness of the right questions. As noted in the 2014 NRC report, we think there is a wealth of information, expertise, and experience to draw upon from the social and behavioral sciences with respect to use of personal and private information under secure conditions and on the protection and management of information. As recommended in the NRC report, guidance offered by the National Institute of Standards and Technology (NIST) that calibrates the
protection of information to levels of risk provides a valuable asset for the Secretary to draw upon in developing safeguard requirements.

- The proposed amendments to the Common Rule include other positive changes important for the protection of research participants and to a system that focuses on research that is more than minimal risk. The simplification of consent statements (though there could be greater attention to consent as a process and not a written document) and the alteration of requirements for continuing review so that it not be required for expedited research or for research no longer in the data collection phase are important improvements to the current Common Rule. Also, as integral to the expedited review procedures, the revision explicitly indicates that the list of categories of research appropriate for expedited review will be reviewed “at least every 8 years.” We encourage a shorter time-span than 8 years but support the commitment to periodic review made explicit in these proposed rulemaking changes. We also encourage explicit language that the list is not exhaustive of nominal risk research that may be appropriate for expedited review as presented by investigators. These recommendations are consistent with the positive steps set forth in the proposed revisions.

Our very positive overall assessment of the NPRM is reason enough to implement changes that make feasible and possible timely revisions to 45CFR46, Subpart A, as set forth above. In that spirit, we offer additional general and specific comments to further consideration and clarification in a final revision of the Common Rule.

**General Comments**

- We support the NPRM’s distinction between excluded and exempt research and its clarification of the types of research in each category. However, we believe that, since this revision involves major changes to the exempt category, the written prose need to be as straightforward as possible. Exempt research at set forth in 46.104 is now subject to new reporting, notification, and information security regulations. The protections are addressed in 46.105. To reduce the complexity and foster user understanding, we encourage OHRP to develop additional guidance for researchers with examples and tables describing the new requirements for different types of exempt research. It would also be of value to offer a table that set forth determinations with respect to research excluded from the regulations.

- We are concerned about the difference between requirements for primary research, such as in 46.104(e)(2), and secondary research at 46.104(f)(1). Investigators are sure to notice that collecting data for secondary research (i.e., for others to use) is more burdensome than collecting data that only they can use. This apparent inconsistency is likely not the intent. Furthermore, it runs against federal policies like the February 22, 2013 Office of Science Technology Policy memorandum “Expanding Public Access to the Results of Federally Funded Research,” earlier data sharing policies at NIH and NSF, and a growing number of journals that require authors to share data supporting their publications (e.g., required by AERA for its scientific journals and homed for journals at ICPSR). We believe that providing broad consent to future research of data should be standard practice in all data collection.

- Under section 46.105(b), the Secretary of HHS will publish a “list of specific measures that the institution or investigator may implement that will be deemed to satisfy the requirement
for reasonable and appropriate safeguards.” Although we value the intent and the commitment to periodic review, as we note earlier, in our opinion, a list of specific measures will be difficult to manage and quickly become obsolete and confusing. A better approach is to specify the threats that investigators must mitigate, such as unauthorized access, interception of network traffic, and theft. We would model these requirements on the approach (but not the level of detail) used by NIST (e.g. Special Publication 800-53 “Security and Privacy Controls for Federal Information Systems and Organizations”), which describes necessary “controls” rather than specific measures to satisfy those controls. ICPSR has many years of experience providing restricted-use data under data protection plans, and we find that lists of specific technologies are extremely difficult to administer. We are moving toward a model in which users will be asked to explain how they are protecting against a list of about ten prominent threats.

- As we illustrate in our comment below related to the NPRM Question 3, we now live in a world where individuals can be re-identified from data that do not include common personal identifiers, like name or social security number. Language in the NPRM is broad enough to cover these situations, and we oppose narrow alternatives, like HIPAA or federal definitions of personally identifiable information. We noted positively the move away from HIPAA above; we want to underscore how important this is for participant protection and the safe use of research by investigators.

- In the ICPSR and SBS White Paper Response to the ANPRM, we endorsed its proposed prohibition against re-identification of de-identified data. Language to this effect is found in the NPRM at 46.101(b)(2)(ii)(B). This language should be extended to all secondary research with data that do not contain individual identifiers. We would like to see a general prohibition against re-identifying subjects without prior consent or appropriate review. This recommendation is consistent with those in the 2014 NRC Report.

Specific Comments

3. To what extent do the issues raised in this discussion suggest the need to be clearer and more direct about the definition of identifiable private information? ... One alternative is to replace the term “identifiable private information” with the term used across the Federal Government. . . .

We urge against using the term “identifiable private information,” because it does not capture all of the risks to privacy posed by research data. Research covered by the Common Rule is increasingly using data collection strategies that allow re-identification of research subjects without the use of attributes that are usually considered personal identifiers. Geospatial coordinates, life histories, and institutional settings (e.g. clinics, prisons, schools) often make data highly identifiable. For example, consider a study of teaching in which the data include grade, subject, and student characteristics (race, ethnicity) by classroom. This information is sufficient to identify teachers. School districts often publish race and ethnicity distributions by school, and it is easy to match aggregate student characteristics to schools. Once schools are identified, there are only a few teachers in each subject and grade. In our opinion, this kind of data should be classified as identifiable under the “may be readily ascertained” standard, but it may not be recognized under the federal standard for personally identifiable information.
9. Public comment is requested on the extent to which covering any of these activities under the Common Rule would substantially add to the protections provided to human research subjects.

The proposed exclusions at 46.101(b)(2)(i) are limited in scope and focus on types of research with minimal risk. It is reasonable to assume that adults can foresee the consequences of responding to these types of data collections. Adults in the United States are accustomed to being asked to participate in surveys, and they refuse to answer much more often than they agree. We also agree with the approach to risk described in 46.101(b)(2)(i)(A) and (B), which distinguishes between the probability of re-identification and the magnitude of harm. This approach was recommended in the NRC report. If data are unlikely to result in re-identification of persons or would cause no harm to them, the research should be excluded.

10. Public comment is sought on whether this exclusion should only apply to research activities in which notice is given to prospective subjects or their legally authorized representatives as a regulatory requirement. If so, please comment on what kind of information should be included in the notice such as the research purpose, privacy safeguards, contact information, ability to opt-out, etc. Would requiring notice as a condition of this exempt research strike a good balance between autonomy and beneficence?

Since this question applies to types of data collection at 46.101(b)(2)(i) that are familiar to the public, we do not believe that extensive notification is necessary. Best practice should be informing subjects of the research purpose and the prospect that the data may be used in secondary research.

11. Public comment is sought regarding whether it is reasonable to rely on investigators to make self-determinations for the types of research activities covered in this particular exclusion category. If so, should documentation of any kind be generated and retained?

AND

13. Public comment is sought regarding whether these exclusions should be narrowed such that studies with the potential for psychological risk are not included. Are there certain topic areas of sensitive information that should not be covered by this exclusion? If so, please provide exemplary language to characterize such topic areas in a manner that would provide clarity for implementing the Rule.

If investigators are provided with a range of examples, they should be able to make this determination themselves. It would be helpful to include examples of topics and questions that respondents might consider sensitive or embarrassing, such as depression. Many of these decisions will require detailed knowledge of a particular research area, and professional associations could be encouraged to provide guidance to researchers.

28. Public comment is sought regarding whether an investigator would be able to contrive his or her responses to the automated exemption decision tool in order to receive a desired result i.e., an exempt determination, even if it does not accurately reflect the research activities.

AND

33. Public Comment is sought regarding the value of adding an audit requirement.
An automated tool will not create incentives for deception that are not already present in other ways of filing information to justify an exemption. A well designed tool can also play an educational role by helping investigators to understand complexities in the regulations. If evidence of deception does emerge, random audits would be an appropriate response. We would support an audit process if it is used rarely and modestly without adding to regulatory burden and in a manner that would allow improved feedback and information to researchers.

34. Public comment is sought on whether this exemption category should only apply to research activities in which notice that the information collected will be used for research purposes is given to prospective subjects or their legally authorized representatives as a regulatory requirement, when not already required under the Privacy Act of 1974. If so, comment is sought on what kind of information should be included in the notice, such as the research purpose, privacy safeguards, contact information, etc. Comment is also sought on how such a notice should be delivered, e.g., publication in a newspaper or posting in a public place such as the school where the research is taking place, or by individual email or postal delivery. Note that other requirements, such as those of the Family Educational Rights and Privacy Act (FERPA) or the Protection of Pupil Rights Amendment, may also apply. Would requiring notice as a condition of this exempt research strike a good balance between autonomy and beneficence?

AND

35. Public comment is sought on whether the privacy safeguards of §11.105 should apply to the research included in §11.104(d)(1), given that such research may involve risk of disclosure of identifiable private information.

As we noted above in our answer to Question 3, data of this kind are often easy to re-identify, and observation of classroom management are used by school districts to make high-stakes decisions about teachers’ pay and employment. In these circumstances, teachers, students and parents should receive notification about research goals, assurances that privacy safeguards will be applied, and contact information.

41. Public comment is sought on whether it is reasonable, for purposes of this exemption, to rely on the exemption determination produced by the decision tool where investigators themselves input the data into the tool, or whether there should be further administrative review in such circumstances.

We think it is reasonable to rely on the tool and urge its development, testing, and periodic refinement.

46. Public comment is sought on whether this exemption category should only apply to research activities in which notice is given to prospective subjects or their legally authorized representatives as a regulatory requirement. If so, comment is sought on what kind of information should be included in the notice such as the research purpose, privacy safeguards, contact information, etc. Would requiring notice as a condition of this exempt research strike a good balance between autonomy and beneficence? Should prospective subjects be given the explicit opportunity to opt out of such research?

Yes, research subjects should be notified when identifiable information about them is collected and stored. Subjects should be given an opportunity to opt out at the time of data collection, but
the notification should cover future use of the data, contact information, and a brief understanding of data protection and security procedures.

49. Public comment is sought on the types of research that should fall under the proposed exemption. Should the proposed exemption be available to all types of research using identifiable data collected for non-research purposes or should the exemption be available only to a more limited subset of research? For example, should the proposed exemption apply only for research using records and information already subject to comprehensive privacy and other protections in other Federal laws (e.g., records held by the Federal Government subject to the Federal Privacy Act, or records governed by HIPAA or FERPA)? Depending upon the scope of the exemption, the relationship between this exemption and the exemption proposed at §II.104(f)(2) would need to be clarified. Since a major justification for including this exemption is to reduce burden on IRBs, should the proposed exemption apply only to research for which IRBs typically waive informed consent, that is, where the research could not practicably be carried out without a waiver of informed consent, and the rights and welfare of subjects will not be adversely affected by the waiver? Finally, is there a sufficient need for this exemption at all given the other proposed exclusions and exemptions?

We consider this exemption for use of data collected for non-research purposes to be very important, but we offer two comments. First, 46.104(e)(2)(ii) implies that some authority is providing the data for a specified purpose. The identity and obligations of that authority are not identified. It would be useful to specify that this authority is obligated to protect the confidentiality of research subjects. Second, a prohibition against the release or publication of information that would lead to the re-identification of subjects (such as 46.101(b)(2)(ii)(B)) would strengthen the protections of private information.

50. Public comment is sought regarding whether the proposed exemption should be limited to research in which individuals had been informed of the potential future research use of their information, and given the opportunity to opt out of having their identifiable private information used for research. If the proposed exemption should be limited in this way, what information should be included in the opportunity to opt out? If the opportunity to opt out is made a condition of the exemption category how should it be structured (e.g., how long and under what circumstances should it remain in effect) and what, if any, impact should the opt out have on other provisions of the rule, such as the ability of an IRB to waive informed consent for a subsequent research study using the individual’s information? Are there other or alternative mechanisms that should be required to respect individuals’ autonomy and other interests?

We believe that allowing subjects to opt-out after data have been collected puts an undue burden on secondary research and creates additional information privacy risks. We expect that many studies will be in this category because of potential re-identification of subjects after direct identifiers (name, SSN, address) have been removed. An unlimited opt-out provision will require retention of direct identifiers, which only increase the risks posed by the data.

61. Public comment is sought on whether broad consent to secondary research use of information and biospecimens collected for non-research purposes should be permissible without a boundary, or whether there should be a time limitation or some other type of limitation on information and biospecimens collected in the future that
could be included in the broad consent as proposed in the NPRM. If a time limit should be required, is the NPRM proposal of up to 10 years a reasonable limitation? Would a limitation related to an identified clinical encounter better inform individuals of the clinical information and biospecimens that would be covered by a broad consent document?

We do not see the benefit of limiting the scope of broad consent with a time limitation or other restrictions. We encourage use of broad consent for future use.

63. Public comment is sought on whether oral consent should be permissible in limited circumstances as proposed under exemption §II.104(f)(1).

If oral consent was appropriate for the original data collection, we agree that it should be sufficient for storage and secondary research.

69. Public comment is sought regarding how likely investigators are to seek broad consent for the use of identifiable private information (as contrasted with biospecimens), given that there are provisions within the NPRM that would make it easier to do such research without consent (such as the new exemption at §II.104(e)(2)). In this regard, note that the NPRM proposal to prohibit waiver of consent by an IRB if a person has been asked for broad consent and refused to provide it might create a disincentive on the part of investigators from choosing to seek broad consent for research involving secondary use of identifiable private information. Given the costs and time and effort involved in implementing the system for obtaining broad consent for the use of identifiable private information and tracking when people provide consent or refuse to do so, are the benefits to the system likely to outweigh the costs, and if so, should the broad consent provisions be limited to obtaining broad consent for research use of biospecimens?

By creating a higher standard for consent for reuse of data with identifiable private information, the NPRM does incentivize the collection of data that will not be available for secondary analysis. Since funding agencies, scientific organizations, and scientific journals have increasingly seen the benefits of data sharing for research participants and the public good, we expect that obtaining informed consent for secondary research will be considered best practice. Of course, this will also depend upon the procedures for obtaining broad consent that will be issued by HHS. If those procedures are perceived to discourage participation by research subjects, fewer studies will meet the criteria for secondary research in 46.104(f) and much will be lost without adding participant protections.

71. Public comment is sought regarding whether particular information security measures should be required for certain types of information or research activities and, if so, what measures and for what types of information or research. Specifically, should the safeguards be calibrated to the sensitivity of the information to be collected?

Yes. We believe that security measures should be calibrated to reflect the two dimensions of risk mentioned above: probability of re-identification and magnitude of harm. Research data vary along both of these dimensions, and security measures should not be unduly restrictive. The research community has developed a variety of measures for protecting sensitive data, including secure remote access systems and enclaves for the most sensitive data.
Investigators and institutions should be allowed to adjust these measures to the risks inherent in each case.

72. Are the proposed limitations on re-disclosure more or less restrictive than necessary? Are there additional purposes for which re-disclosure of biospecimens or identifiable private information should be permitted?

We would prefer a policy that focused attention on the obligation to protect subjects, rather than the approach found at 46.105(c). The requirements listed 46.105(c) provide guidance for transferring identifiable information between researchers or institutions, but important risks to subjects are not considered. For example, statistical results can be published in ways that would allow for the re-identification of subjects. Data use agreements in the social sciences often include restrictions on publications designed to protect subjects, such as requiring a minimum number of cases in every cell of a table. Again, we recommend use of language as in 46.101(b)(2)(ii)(B) that would create a broad obligation to protect the private information of research subjects.

We appreciate the opportunity to offer our overall assessment as well as general and specific comments. We stand ready to provide additional help and advice were it to be useful. We appreciate the dedication of human research experts and science policy leaders within the Office for Human Research Protections, the Office of Science and Technology Policy, the Office of Management and Budget, and at the other Federal agencies and departments committed to a strong, vital, and forward looking Common Rule.

Sincerely,

Felice J. Levine, PhD
Executive Director
American Educational Research Association
and
Chair, Board of Directors
Consortium of Social Science Associations

George Alter, PhD
Director
Inter-university Consortium for Political and Social Research
University of Michigan

Wendy Naus
Executive Director
Consortium of Social Science Associations
About AERA
The American Educational Research Association (AERA) is the national scientific association for more than 25,000 members engaged in research on education. AERA aims to advance knowledge about education, encourage scholarly inquiry related to education, and promote the use of research to improve education and serve the public good. AERA embraces the role of improving the nation’s education research capacity by promoting application of scientific standards; by a special emphasis on research ethics and the responsible conduct of research; and by providing training programs, research and mentoring fellowships, and seminars on professional and methodological issues. AERA publishes seven peer reviewed journals (including AERA Open—an open access journal), issues Standards for Reporting on Empirical Social Science Research in AERA Publications, and promotes the highest standards for research integrity through its Code of Ethics.

About ICPSR
The Inter-university Consortium for Political and Social Research (ICPSR) is the world’s largest archive of social science data. More than 100,000 users download data from ICPSR every year. Since our creation in 1962, we have expanded to provide quantitative data across all social science disciplines. The Consortium includes more than 750 universities and research organizations located around the world, and we disseminate data for a range of government agencies and other groups, including the Bureau of Justice Statistics, the National Institute on Aging, and the National Collegiate Athletic Association. Our archive has more than 8000 research collections, some of which include hundreds of datasets. The highly regarded ICPSR Summer Program in Quantitative Methods offers more than fifty courses every summer to a thousand participants. ICPSR was also one of the founding members of the Data Documentation Initiative (DDI), which has become an international standard for metadata in the social sciences, and we provide the home office for the DDI Alliance.

About COSSA
The Consortium of Social Science Associations (COSSA) is a nonprofit national organization serving as a united voice for more than 100 professional associations, scientific societies, research centers and institutes, and colleges and universities that care about a robust social and behavioral scientific research enterprise. We represent the collective science policy interests of all fields of social and behavioral science research, including but not limited to sociology, anthropology, political science, psychology, economics, statistics, language and linguistics, population studies, law, communications, education research, criminology and criminal justice research, geography, history, and child development. We further work with the broader scientific and higher education communities to ensure that federal policies and funding continue to advance the U.S. scientific research enterprise.