

AAU Association of American Universities
COGR Council on Governmental Relations
NASULGC National Association of State Universities and Land-Grant Colleges

February 2, 2001

Committee on Assessing the System for Protecting Human Research Subjects
Daniel Federman, M.D., Committee Chair
Board on Health Sciences Policy
The National Academies
2101 Constitution Avenue, NW FO-3108
Washington, DC 20418
ATTN: Dr. Laura Lyman Rodriguez

Dear Dr. Federman,

This letter presents comments of the Association of American Universities (AAU), the Council on Governmental Relations (COGR) and the National Association of State Universities and Land-Grant Colleges (NASULGC) on the proposed Public Responsibility in Medicine and Research (PRIM&R) accreditation standards for the protection of human subjects research on which the Institute of Medicine has sought commentary.

The AAU is an organization of research universities devoted to maintaining a strong system of academic research and education, and consists of 59 U.S. universities and two Canadian universities. COGR is an association of 143 research-intensive universities that concerns itself with the influence of government regulations, policies and practices on the performance of research conducted at colleges and universities. NASULGC, with roots back to 1887, is the nation's oldest nonprofit higher education association with 210 members from all 50 states, the District of Columbia and the U.S. territories.

Our organizations and the institutions we represent are committed to ensuring the safety and dignity of human subjects as new treatments and therapies are developed and tested and new knowledge is gained about human interactions through research in social and behavioral sciences. When this important research is conducted consistent with the highest ethical standards and with applicable laws and regulations, the public can have confidence that human subjects are being properly treated. Voluntary accreditation can play an important role in ensuring that the highest standards are achieved. Specifically, we support the establishment of a non-profit organization dedicated to conducting high-quality voluntary accreditation, following the PRIM&R standards (as we suggest they be modified in this letter), such as the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

We appreciate the opportunity to comment on the draft standards. We hope we can work together toward developing accreditation standards that promote the outcome of achieving the highest ethical standards and compliance with regulations while avoiding prescriptive accreditation standards.

General Comments

In May 2000, the Association of American Universities and the National Association of State Universities and Land-Grant Colleges approved the *Statement of Good Practices in the Establishment of Specialized Accreditation Standards* (Attachment 1). This statement was developed by a task force of provosts from AAU and NASULGC institutions to help accreditors and universities work together to find effective and efficient ways of meeting accreditation standards. Where applicable, we have applied the central tenets of this statement to the draft PRIM&R standards.

Standards should express the existing laws and accepted norms for a system of human subjects research protection. Issues of resources, organization, and staffing should be made by the individual institutions to preserve flexibility and independent decision making.

Resources: Although allocation of resources is an area of relevant concern for issues related to human subjects research, we do not believe that a standard should specify that allocation. Accrediting bodies must not dictate specific funding requirements, unless it is specified in local, state or federal laws and/or regulations. Accreditation standards which include or result in specific amounts for space, salaries, workloads or other standards that impact institution resources can be counterproductive.

Organization: Accreditation standards should not prescribe the organizational structure of a program or the organizational relationship of the program to the institution. What is appropriate for one institution's organizational structure may be inappropriate for another.

Exceeding existing regulatory language: Standards for accreditation should generally not exceed state, local, and federal regulations. Requirements beyond what is mandated by regulations or law are a troublesome signal of excessive intrusiveness of an accrediting body.

Overall, the standards and the "commentary" provide a confusing package, mainly because the role and relative weight of the "commentary" are not specified. It is not clear to what extent the "commentary" is intended to be descriptive or prescriptive. Can, for example, an institution be accredited if it meets the stated standard but uses a different implementation method than the one that is specified in the "commentary"? If not, does that mean that the "commentary" is really the standard? If so, what is the status of the "commentary"? We also found the statements labeled "commentary" to be uneven. Some were the type of text that should be contained within the standards themselves, some merely repeated the standards, and others were informal observations. Still others would significantly impinge upon institutional flexibility and decision-making. We therefore recommend removing all of the "commentary" sections, though we also suggest moving some of the "commentary" text into the standards themselves, as described in detailed comments below.

Since much of the "commentary" provides examples of processes that would be in compliance with the standards, we suggest that IOM, in conjunction with OHRP and PRIM&R, consider developing a "best practices" document that would contain the portion of this "commentary" text that is comprised of examples. This could be similar to the National Research Council's "Guide for the Care and use of Laboratory Animals," which is quite helpful to institutions seeking accreditation of their animal care facilities.

Specific Comments on Standards of Concern

1.3 The organization must place the responsibility for its HRPP in an institutional official with sufficient standing and authority to ensure implementation of the program.

Comment: The standard itself is reasonable, but the “commentary” is particularly objectionable as an example of the type of intrusiveness that must be avoided. We recommend removal.

1.5 The governance of the organization must assure the independence and credibility of its IRB(s).

Comment: It would be preferable to incorporate part of the draft commentary in this standard. As a result the standard would read, "The governance of the organization must assure the independence and credibility of its IRB(s). The IRB(s) should have a clear mechanism for managing any influence that blocks or otherwise interferes with its functions." This change will clarify the standard's intent of what is meant by independence and credibility.

1.10 The organization must provide sufficient staff, space, equipment, finances, technology, and other resources for its HRPP.

Comment: This standard should be rewritten to allow for institutional autonomy in allocation of resources. Our recommended wording replaces the current draft standard with the final line of the draft commentary: "The organization should provide sufficient resources to its HRPP for the accomplishment of its role."

1.14 The organization must utilize a system for continuously assessing and improving the performance of its HRPP. This system, that examines results or outcomes of the HRPP's activities, must include the identification of problems, implementation of interventions, and measurement or evaluation of the effect of interventions.

Comment: We applaud continuous assessment and evaluation of HRPPs, which in many cases can lead to institutional changes and improvements. We recommend, however, reflecting the reality that an assessment may not require any changes, by modifying the standard to insert “, as necessary,” between “and” and “improving” in the first line.

In addition, it is vital to recognize the difference between an institution's responsibility for having a system of evaluation and assessment and having an accreditation team dictate what is to be done with the outcomes of such a system. Accreditation team recommendations for improvement, whether based on their own analyses or information gleaned from institutions’ systems of continuous assessment and improvement, must not become requirements on which current or future accreditation is based.

1.15 The organization must have policies or procedures describing how it communicates with the community it serves and those individuals at risk in that community that may be involved in research.

Comment: It is difficult to understand the intent of this standard, which is further complicated by the commentary that seems to mistakenly equate issues related to cultural sensitivity and risk to special populations. Since this item also exceeds regulatory requirements, we recommend that this standard be eliminated.

SECTION 2 - INSTITUTIONAL REVIEW BOARDS (IRBs)

Comment: The "general commentary" under Section 2 is particularly troublesome, since it is quite prescriptive and provides a level of detail that is not warranted in the standards. It should be deleted.

2.2 The IRB(s) must identify to the appropriate institutional officials the resources it requires.

Comment: It is not clear why this standard is necessary. IRB officials are expected to provide information on their resource requests in the course of institutional operations. Inclusion of all such details would be burdensome. We recommend removal of the standard.

2.4 The IRB chair(s) must possess sufficient respect within the organization and the leadership skills necessary to lead the IRB(s) and be an authority on the protection of human subjects in the HRPP.

Comment: We concur that IRB chairs should have these skills and characteristics. However, determination of whether someone meets this standard will be difficult, and it is an inappropriate role for an accrediting body to require such a measurement. This standard should therefore be eliminated.

2.5 Knowledge, Skills and Abilities.

The IRB administrator, staff, chair(s) and Board members must possess and maintain knowledge, skills and abilities appropriate to their role pertaining to at least the following:

- **General ethical principles and concepts underlying the conduct of research involving human subjects;**
- **Applicable Federal, state, and local regulations;**
- **Applicable HRPP and IRB policies and procedures;**
- **Role of the IRB(s) in the HRPP; and**
- **These accreditation standards**

Comment: This standard should reference existing legal requirements for education and training of those involved with an IRB. Please insert “, consistent with requirements promulgated by HHS’ Office of Research Integrity and Office of Human Research Protections,” between “role” and “pertaining” in the second line.

(B) The IRB chair must possess and exercise leadership skills and expert knowledge about the protection of human subjects.

Comment: This standard is unnecessary, since the measurable parts of it are covered in other proposed standards (e.g., 2.5A), and the other portions are unmeasurable. It is inappropriately intrusive and should be removed.

(C) The individual responsible for the administration of the IRB must possess and exercise administrative abilities required to guide the IRB(s) for which he/she is responsible.

Comment: This standard is unnecessary, since its measurable parts are covered in other standards (e.g., 2.5A). It is also intrusive and should be removed.

2.9 The IRB must determine that the consent process is appropriate for the circumstances under which the research will be conducted.

Comment: The idea contained in the last sentence of the “commentary” for this draft standard should be added to the standard itself, so that the revised standard reads: "The IRB must determine that the consent process is

appropriate for the circumstances under which the research will be conducted. The Principal Investigator (PI) of the study is responsible for all aspects of the consent process, in all circumstances."

2.11 The IRB must have written policies and procedures pertaining to the following and relevant to the types of research reviewed:

...

(H) Investigators' conflicts of interest

...

Comment: The standard needs to be modified to reflect the fact that federal statutes and regulations vest institutional responsibility for managing individual financial conflict of interest processes in institutional officials or committees which are not the same as the IRB's – the draft "commentary" notwithstanding. The standard should be rewritten to reflect these other statutes, regulations, and, as noted above, the "commentary" text should be removed. Revised standard text could read as follows: "Investigators' conflicts of interest, consistent with institutional policies governing the management of conflicts of interest, will be evaluated and managed as required by federal regulation."

2.13 IRB minutes, record keeping, and retention requirements

(A) The IRB meeting minutes must include at least the following information:

- (1) Approval of minutes from the previous meeting**
- (2) Attendance at meetings**
- (3) Actions taken**
- (4) Votes (including total present) for, against, and abstaining, as well as names of abstainers, and reason for abstention, if appropriate**
- (5) Documentation indicating retention of quorum throughout meeting**
- (6) Summary of the discussion of issues and their resolution (including, when appropriate, minority reports)**
- (7) Basis for requiring changes, deferring, or disapproving protocols**
- (8) Special findings (i.e., criteria for varying or altering consent requirements or risk categories for children and other vulnerable populations)**
- (9) Discussion of the need for a DSMB or other monitoring procedure(s)**
- (10) When appropriate, determination of significant/non-significant devices (for studies under the auspices of FDA investigational device regulations)**
- (11) Requirements for frequency of continuing review, if more often than annually**

Comment: This standard should be transformed from a detailed list, which could allow the overall point to be missed, into an outcome goal, consistent with good accreditation practices. The standard should instead read, "The minutes must include a clear record of the decisions made, the votes taken (including abstentions), maintenance of a quorum, and any special circumstances surrounding a decision."

(B) The IRB files must include an IRB roster, members' qualifications, and organizational assurances including any relevant appendices, when appropriate.

Comment: This standard should be changed to "The IRB files should include information necessary to document that the organization is in compliance with institutional and regulatory requirements."

3.6 Principal Investigators must conduct research involving human subjects only when supported by adequate resources including staffing, time allocated by the staff to the research, funding, space, record-keeping capability, and back-up for adverse events.

Comment: This should be changed to "Principal investigators must conduct research involving human subjects only when supported by adequate resources, consistent with institutional and regulatory requirements."

3.7 Investigators must appreciate and acknowledge the organizational environment in which they conduct research and their position in the HRPP.

Comment: This standard is vague and it is not clear how it would be measured. It should therefore be eliminated.

In conclusion, we support efforts to develop accreditation standards for human subjects protections systems, and appreciate the effort that PRIM&R and IOM have put into developing these materials. We appreciate the opportunity for the community to comment. We hope that the draft standards and "commentary" can be modified as we suggest above, and look forward to working with IOM and PRIM&R as this process continues. If you have any questions about any of our comments, please contact Richard Turman at AAU, Rich Harpel at NASULGC, or Tony DeCrappeo at COGR.

Thanks for your consideration of our suggestions.

Cordially,



Nils Hasselmo
President, AAU

Katharina Phillips
President, COGR

C. Peter Magrath
President, NASULGC

cc: Sandy Chodosh, PRIM&R

STATEMENT OF GOOD PRACTICES IN THE ESTABLISHMENT OF SPECIALIZED ACCREDITATION STANDARDS

We have developed this statement of good practices to help accreditors and institutions work together to find effective and efficient ways of meeting specialized accreditation standards. It is a central tenet of our statement that specialized accreditation standards must be based on educational outcomes. By "outcomes" we do not mean to signal that we embrace the results of standardized outcomes tests as the appropriate measure. A graduate's ability to perform in his/her field of study can be measured by a variety of indices, and we expect much creativity in outcomes measurement to result from this focus.

Because there are many ways to achieve desired educational outcomes, standards based on outcomes focus on achieving those desired ends rather than on prescribing specific resources or organizational structures. Unless demonstrable relationships exist between inputs or organizational arrangements or facilities or given sets of circumstances and desired student outcomes, such prescriptive standards are arbitrary. Furthermore, because outcomes measures must be specific to both standards and institutions, the accredited programs themselves must be able to determine the best ways to produce those outcomes. If accreditors specify how education is to be delivered, they may well inhibit innovations that could more effectively produce desired outcomes. Institutions must be free to experiment if we want to progress.

Thus, we firmly believe that desired educational outcomes form the only legitimate basis for specialized accreditation standards. Matters not relating directly to student outcomes simply are not legitimate subjects for such standards. So long as standards that have unproven relationships to student outcomes remain, institutions and the public will question their legitimacy.

We acknowledge that accreditation standards should assure students, faculty, the institution, the profession and the public that graduates of a program meet prescribed standards. We also acknowledge the opportunity that specialized accreditation provides to improve program quality in areas unrelated to student outcomes through collegial consultations. But, the two must remain distinct. Institutions are responsible for the quality of all programs offered and, once prescribed standards are met, must therefore be able to target effort and resources toward quality improvement in accredited programs within the context of overall institutional priorities. Unless judgment about prescribed standards is kept separate from recommendations about quality improvement it is not possible for institutions to exercise their responsibility in this regard. Thus, meeting standards should lead to a program's accreditation. Program improvement ought to be embraced if the institution judges that making recommended change is consistent with its own priorities.

The award to a program of specialized accreditation provides:

- students with the assurance that the education that they receive is designed to prepare them for entry into the profession
- employers and the public with the assurance that accredited program graduates have received an education designed to prepare them for entry into the profession
- the profession with assurance that accredited programs adhere to the standards prescribed
- universities with external validation that their programs have met prescribed minimum standards

To achieve these ends and to do so in an environment in which responsibility for them is shared with the faculty and universities in which the programs are taught, accreditation standards will:

- focus on the students' acquired knowledge, skills and abilities that are demonstrably related to the needs of the profession, i.e., focus on the desired student outcomes and judge outcomes from a variety of indices
- involve accredited programs in the assessment of student knowledge and skills
- judge the program in its current state, not on speculation about possible future states

Accreditation standards and actions will not:

- prescribe the resources the accredited programs will utilize
- prescribe the organizational structure of the program or the organizational relationship of the program to the university that houses it

- prescribe conditions to be met by the University or other programs within the University
- set standards for programs within the University it does not accredit nor condition accreditation of programs it does accredit on their relationship to or control over other programs within the University
- prescribe conditions of employment for faculty or staff, including workloads and compensation
- prescribe standards or conditions that will inhibit educational innovation
- prescribe standards or conditions that bear on matters not directly related to educational outcomes
- impose standards that are higher than those required by law in areas that do not bear directly on educational outcomes
- prescribe the source from which funding for the accredited program or its activities will come

Some accreditors have pursued practices that make it difficult to adhere to the institutions' public responsibilities to be cost-effective. These Good Practices are intended to enable accreditors and accredited institutions to work more constructively to achieve common goals.

*Approved: Association of American Universities
National Association of State Universities and Land-Grant Colleges
May 2000*

10/18/2000