Subject: Revision of Researcher Certification and Institutional Review Board (IRB) Protocols (Resolution 11-A-17)

Presented by: Gerald E. Harmon, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Peter H. Rheinstein, MD, JD, MS, Chair)

Resolution 11-A-17, “Revision of Researcher Certification and Institutional Review Board (IRB) Protocols,” sponsored by the Florida Delegation, was referred by the House of Delegates in June 2017. This resolution asks our AMA to:

[S]tudy existing Collaborative Institutional Training Initiative standards, Institutional Review Board protocols and create recommendations that would simultaneously protect patients and permit physicians to easily participate in the dissemination of medical knowledge.

HUMAN SUBJECTS PROTECTIONS

Concerns about the ethical conduct of research involving human participants date back to the 19th century, well before the evolution of the current regulatory framework in the U.S. [1]. The principles underlying the current system of oversight of human subjects protections were set out in the 1979 Belmont Report by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research [2], and subsequently codified in regulations adopted by the Department of Health and Human Services (DHHS) and by 14 departments and agencies a decade later—the “Common Rule” [3]. The Common Rule sets basic standards for research oversight, including the establishment of institutional review boards (IRBs) and review procedures, and criteria for individual informed consent [4]. The goal of this—and similar regulatory efforts in other countries—is to protect the rights and well-being of individuals who participate as subjects in biomedical and behavioral research.

The Common Rule has been criticized as ineffective, cumbersome, and of questionable value in actually protecting research participants [5-7]. A 2011 review of empirical studies indicated, for example, that there is considerable variation in IRB structure, membership, processes, and in outcomes of IRB reviews [6]. A recent study of whether and how essential elements of human subjects protection are implemented during institutional review or research protocols found considerable variation among 20 participating IRBs [8]. The current system of oversight has also been critiqued as unable to address effectively the challenges of today’s research landscape, especially in light of the increasing prominence of multi-site research involving large numbers of participants and research involving large data sets or collections of biospecimens, and their implications for informed consent [9].

In 2011, the DHHS launched a review and reassessment of the Common Rule, issuing an Advanced Notice of Proposed Rule Making (ANPRM) seeking public comment to enhance protection of research subjects and improve the process of research review [10].
Four years later, DHHS issued a Notice of Proposed Rule Making (NPRM) soliciting comment on proposed updated policy. Stakeholders opposed the NPRM’s proposal to require consent for secondary research use of unidentified biospecimens, but supported proposals for improving informed consent, especially for simplifying consent forms while suggesting some modifications, which are reflected in the Final Rule issued in January 2017 [11-12]. The Final Rule also retains provisions intended to reduce unnecessary regulation and streamline oversight processes, including creating new categories of exemption from IRB review for low-risk studies, eliminating the requirement of continuing review for some categories of research, and introducing new options for facilitating screening of prospective participants. (On January 19, 2018, DHHS issued notice that it would delay the compliance deadline for the updated Common Rule to July 19, 2018 [13].)

In 2008 and 2009, AMA shared its concern that over interpretation of Common Rule protections in the context of quality improvement activities imposed unnecessary regulatory burdens on important research [14-16]. AMA also provided input under the auspices of the Advanced Notice of Proposed Rule Making [17] and the Notice of Proposed Rule Making [18].

EDUCATING THE RESEARCH COMMUNITY ABOUT HUMAN SUBJECTS PROTECTIONS

The National Institutes of Health requires that “key personnel” on NIH-funded research involving human subjects receive education on protecting human subjects [19]. These include principal investigators and all other individuals who are responsible for the design or conduct of the research, including foreign awardees or foreign subcontractors and third party personnel or consultants, even if they are not compensated through the NIH award, as well as investigators involved in research that is exempt from IRB review. Investigators in research with human specimens, tissues, or data that has been determined not to involve human subjects in keeping with guidance from the Office for Human Research Protections (OHRP) are not required to fulfill the educational requirement, nor are personnel who are not involved in the design and conduct of human subject research. NIH leaves the decision of what educational programs to use to meet this requirement to investigators' home institutions. The NIH Clinical Center offers free online education that institutions may elect to meet the education requirement.

In addition, the Collaborative Institutional Training Initiative (CITI) offers web-based education in human subjects protections developed by experts in research ethics, ethics committee process, and web-enabled learning [20-21]. Initially created in 2000 in response to the then newly announced NIH education requirement for agency grantees, CITI’s offerings have expanded over time to encompass a robust catalogue of instruction in multiple aspects of the responsible conduct of research. Modules are available to learners through institutional subscriptions (at a current cost of $3,400/year) or for purchase by individuals (“independent learners”) (currently $130/module).

Training is also available specifically for IRB members. OHRP, for example, offers periodic workshops on various topics in human subjects protections and has developed extensive policy guidance. It also offers practical tools to clarify interpretation of the Common Rule and help IRBs evaluate research protocols effectively; for example, decision charts to help IRBs answer such key questions as whether a proposed study involves human subjects, whether it is exempt from IRB review (or eligible for expedited review), or whether informed consent may be waived. OHRP Educational resources for IRBs are also available through organizations such as Public Responsibility in Medicine and Research (PriMR), which offers certification for IRB professionals [5].

Although there are reservations about their effectiveness in meaningfully protecting human subjects, efforts have also been launched to accredit IRBs. Thus the Association for the
Accreditation of Human Research Protection Programs (AAHRPP) promotes quality standards and performance improvement for IRBs and institutional human research protection programs [6].

INSTITUTIONAL AND JOURNAL POLICIES

Institutions that carry out federally funded research, as well as professional journals that publish the findings of research with human subjects have similarly established expectations that research personnel will adhere to human subjects protections in keeping with federal regulations. For example, the University of Illinois at Champaign Urbana requires that researchers complete CITI’s “Core Basic Training for either social/behavioral research or biomedical research,” and more specialized modules as may be needed for the purposes of specific studies, such as those involving children [22]. The University of California-Berkeley likewise requires that faculty, students, and staff engaged in human subjects research complete appropriate CITI [23], while San Francisco State University requires “all researchers using research volunteers to pass an online research training course,” and provides links to both NIH and CITI courses [24]. Other institutions—e.g., Vanderbilt University School of Medicine [25], Duke University School of Medicine [26]—require completion of in-person courses or other educational programs developed by the institution to address NIH educational requirements for research carried out with human subjects.

Professional journals frequently require that authors reporting findings of social/behavioral or biomedical research with human subjects attest that the study presented adhered to human subjects protections and appropriate oversight. The International Committee of Medical Journal Editors (ICMJE) recommends that investigators ensure that “the planning, conduct, and reporting of human research” is in accord with the Declaration of Helsinki, the international statement of research ethics promulgated by the World Medical Association [27]. The Journal of the American Medical Association and JAMA Network journals, for example, require that authors of manuscripts reporting studies that involve human participants or animals submit documentation demonstrating formal review and approval (or waiver) of the research and describe the review and its determination [28]. Annals of Internal Medicine likewise requires authors to confirm appropriate review or affirm that the research reported is consistent with the principles of the Declaration of Helsinki [29], while The Lancet advises prospective contributors that it adheres to the ICMJE Recommendations [30].

AMA POLICY


CONCLUSION

Oversight of research that involves human participants must balance important interests of science, the community, and individuals. Commitment to protecting the well-being and rights of individuals who agree to participate in research is fundamental to the ethics of the medical profession and to public trust.
Significant attention has been given in recent years to enhancing the system of research oversight in ways that sustain robust protections for human participants while streamlining processes of review and oversight and minimizing the burden on investigators. As scholars recently noted in relation to the Common Rule, “In an age of big data and cybersecurity threats, and as new technologies reveal personal identities, ethics rules become even more important. Federal oversight will remain the bulwark against unethical practices. In the end, treating human research participants with respect and fairly is essential for continuing public support of vital scientific investigations” [31].

RECOMMENDATION

In light of the importance of protecting the well-being and rights of research participants and the considerations reviewed above, your Board of Trustees recommends that the following be adopted in lieu of Resolution 11-A-17, “Revision of Researcher Certification and Institutional Review Board (IRB) Protocols,” and the remainder of the report be filed:

That our AMA continue to support efforts to improve protections for human subjects of biomedical and behavioral research and advocate for change as opportunities arise. (New HOD Policy)

Fiscal Note: Less than $250
REFERENCES

14. Edward L. Langston, MD, Chair to Samuel Tilden, MD, JD, LLM, Chair, Secretary’s Advisory Committee on Human Research Protections. January 18, 2008.
17. James L. Madara, MD, EVP to Jerry Menikoff, MD, JD, Director, Office for Human Research Protections, October 26, 2011.
18. James L. Madara, MD, EVP to Jerry Menikoff, MD, JD, Director, Office for Human Research Protections, January 5, 2016.


