

COMMITTEE ON HUMAN RESEARCH (CHR) ANNUAL REPORT

2018

Members: Emil Chiauzzi, (Chair), Cinnamon Bloss, Mary Cwik, Janine Jennings, Leah Light, Simon Rosser, Karen Saules, and Sangeeta Panicker (APA Staff Liaison).

In keeping with its mission to facilitate the conduct of and training in scientifically and ethically responsible research involving humans, in 2018 the Committee on Human Research (CHR) focused its efforts on education, outreach, and regulatory issues.

Education and Outreach Initiatives

Ethical Issues in the Use of New and Emerging Technologies in Psychological Science: Given the ubiquity of mobile and digital technologies in everyday life as well as the increased use of emerging technologies in the conduct of research with human participants, the Committee initiated a multi-year and multi-pronged project aimed at guiding psychological scientists in navigating the changing research landscape and associated ethical dilemmas and ethically incorporate emerging technologies in the conduct of psychological research with human participants.

Policy & Regulations

Revised Common Rule: On January 19, 2017 the final revised Federal Policy for the Protection of Human Subjects (45 CFR 46, Subpart A), also known as the Common Rule, was published in the Federal Register by the U.S. Department of Health and Human Services (HHS). CHR reviewed the revised rule to determine how it might affect the regulation of behavioral, cognitive, and psychological research. Concluding that the final rule included many changes that were misdirected and would likely neither reduce regulatory burden nor enhance the protection of human research participants, the Committee identified potential mechanisms for providing constructive input to regulators and institutional review boards (IRBs) on the judicious application of the new regulations to behavioral, cognitive, and psychological research. However, CHR also noted that because of the hold on all new regulations imposed by the new administration, there was much uncertainty about if and when the new regulations would go into effect. Thus, CHR decided to continue monitoring the regulatory progress and to table further discussions about potential CHR initiatives focused on the new regulations, until the fate of the revised regulations is determined. On January 22, 2018, HHS issued an Interim Final Rule that delayed the effective and general compliance dates of the 2018 Common Rule, until July 19, 2018, to provide additional time to both regulated entities for the preparations necessary to implement the 2018 Requirements. On April 20, 2018, HHS issued a NPRM soliciting public comments, within 30 days, to a proposal to delay by an additional six months the general compliance date, while allowing the use of three burden-reducing provisions from the 2018 Common Rule, during the delay period. With input from CHR and individual APA members, staff submitted official APA comments to HHS Office for Human Research Protections (OHRP).

Resolution Supporting Mature Minors' Ability to Participate in Research: The impetus for this resolution was a commentary that was published in 2016 that highlighted institutional review board (IRB) barriers to research with gay/bisexual teens. conduct research with minors, when the focus of the study is HIV/AIDS as well as other sexual or risky health behaviors. IRBs will often impede the ability to conduct such research with minors, by interpreting and applying current regulations in an overly conservative and rigid manner and requiring parental permission for minors' participation in research. However, obtaining parental permission for participation in research on sensitive or stigmatized issues may put the minor at risk of harm. Furthermore, some states allow mature minors to seek health care without parental permission. Thus, CHR drafted an APA resolution that affirms the importance of research on sexual health (and other risky) behaviors with mature minors and the need for judicious regulation of such research in a manner that affirms the principle of autonomy and respects the inherent rights of parents as well as mature minors. The resolution was adopted as APA policy by the APA Council of Representatives at its August 2018 meeting.

Future plans and development of new initiatives

CHR generated a list of potential initiatives for the Committee and began to prioritize them. The short list includes:

- **Learning Health Care System:** The Committee discussed the research ethics implications of the impetus for organizing American health care as a Learning Health Care System. Member Barton Palmer gave a short presentation demonstrating how this concept is relevant to clinical psychology research, in which patient care becomes research. Members also discussed the relevance to comparative effectiveness studies for treatments. The Committee will track the issue as it evolves.
- **Advocating for Psychological Science:** Members discussed issues of concern within the scope of psychological research, such as funding and grant writing reimbursement, reproducibility and replication studies in the face of diminishing research budgets, and informed consent used as a form of risk management. The Committee decided to maintain awareness of these issues and be ready to respond with a clear message to legislators, regulators, and agency staff, as necessary.

Membership Changes

Cinnamon Bloss, Emil Chiauzzi, Mary Cwik, Janine Jennings, and Simon Rosser continued to serve on the Committee during 2018 and were joined by Leah Light, and Karen Saules. While Dr. Jennings resigned from the Committee late in the year, Drs. Bloss and Cwik, rotated off the Committee at the end of 2018, and were replaced by Valentina Ivezaj, Marguerita Lightfoot, and Maria Marquine in 2019. The Committee elected Simon Rosser to serve as Chair in 2019.