Abstracts of Note: The Bioethics Literature

This section is meant to be a mutual effort. If you find an article you think should be abstracted in this section, do not be bashful—submit it for consideration to feature editor Kenneth V. Iserson care of *CQ*. If you do not like the editorial comments, this will give you an opportunity to respond in the letters section. Your input is desired and anticipated.

Ness RB. Influence of the HIPAA Privacy Rule on health research. *JAMA* 2007; 298(18):2164–70.

With anecdotal reports suggesting that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule may be affecting healthcare research in the United States, these authors surveyed epidemiologists about their experiences with the HIPAA Privacy Rule. They had 13 epidemiology societies distribute a national web-based survey; 2805 respondents accessed the survey website and 1527 eligible professionals anonymously answered questions ranking their perceptions of Privacy Rule influence on 5-point Likert scales. Their responses detailed research delays and added costs after Privacy Rule implementation, the frequency and type of Privacy Rule-related institutional review board modifications, the level of difficulty they had obtaining de-identified data and waivers, their experiences with multisite studies, and their perceived participant privacy benefits under the Rule. A total of 875 (67.8%) respondents reported that the HIPAA Privacy Rule has made research more difficult at a level of 4 to 5 on a Likert scale, in which 5 indicates a great deal of added cost and time to study completion. A total of 684 (52.1%) respondents identified a "most affected" protocol. Respondents indicated that the proportion of institutional review board applications in which the Privacy Rule had a negative influence on human subjects' (participants') protection was significantly greater than the proportion in which it had a positive influence ($p < .001$). The authors concluded that, *of the clinical scientists surveyed, only a quarter perceived that the HIPAA Privacy Rule has enhanced participants' confidentiality and privacy, whereas the Rule was perceived to have a substantial, negative influence on human subjects health research, often adding uncertainty, cost, and delay. Not part of this study, but having a greater negative impact on patient welfare, is the difficulty clinicians have in obtaining necessary information from other institutions and practitioners about the patients they are treating—even in life-threatening circumstances.*

Baker A. Patient involvement in a professional body: Reflections and commentary. *Journal of Health Organization & Management* 2007;21(4–5):460–9.

This paper discusses the issues that emerge when an autonomous, professional, member-led organization attempts to demonstrate its accountability to patients through involving lay individuals in its standard-setting processes. The author reports on an ongoing project that is described as "action research." Based on data collected through participant observation in a series of discussions and working groups and a limited literature search that found little relating to lay involvement in professional bodies, the study found that *patient involvement in a professional body is unlikely by itself to be a useful mechanism for delivering greater professional accountability*. Although this paper represents only a single case study, little else is available about this growing policy trend. The author notes that professional bodies of various types are increasingly being asked to demonstrate public involvement in their decision-making. It is important to identify the most effective mechanisms for this, as well as the limitations inherent in the structures of such organizations, which are accountable primarily to their members.

McClure KB, Delorio NM, Schmidt TA, Chiodo G, Gorman P. A qualitative study of institutional review board members' experience reviewing research proposals using emergency exception from informed consent. *Journal of Medical Ethics* 2007;33(5): 289–93.

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Emergency exception to informed consent regulation was introduced in the United States to provide a venue to perform research on subjects in emergency situations before obtaining informed consent. For a study to proceed, institutional review boards (IRBs) need to determine if the regulations have been met. Of course, IRB members must know and understand these rules to determine if study protocols meet them. Little is known about IRB members' views of exception to consent. These authors attempted to determine IRB members' experiences in reviewing research protocols that used emergency exception to informed consent. They used semistructured telephone interviews to survey 10 selected IRB members from around the United States. Interview questions focused on the length of the review process, ethical and legal considerations, training provided to IRB members on the regulations, and experience using community consultation and notification. Content analysis was performed on the interview transcripts. To ensure validity, individuals with varying backgrounds (three emergency physicians, an IRB member, and a layperson) conducted the data analysis. Survey respondents noted that (1) emergency exception to informed consent studies requires lengthy review; (2) community consultation and notification regulations are vague and hard to implement; (3) current regulations, if applied correctly, protect human subjects; (4) legal counsel is an important aspect of reviewing exception to informed consent protocols; and (5) IRB members have had little or no formal training in these regulations, but are able to access materials needed to review such protocols. Based on this preliminary study, these authors concluded that *IRB members find emergency exception to informed consent studies take longer to review than other protocols, and that community consultation and community notification are the most difficult aspects of the regulations with which to comply, but that they adequately protect human subjects*.

Gotzsche PC, Hrobjartsson A, Johansen HK, Haahr MT, Altman DG, Chan AW. Ghost authorship in industry-initiated randomised trials. *PLoS Medicine* 2007;4(1):e19.

The assumption that the listed authors have actually written a peer-reviewed scientific article has been justifiably questioned. Ghost authorship, that is, the failure to name an individual who has made substantial contributions to an article as an author, may result in a lack of accountability. Because the prevalence and nature of ghost authorship in industry-initiated randomized trials was not known, these authors conducted a cohort study comparing protocols and the corresponding publications for industry-initiated trials approved by the Scientific-Ethical Committees for Copenhagen and Frederiksberg. They defined a paper as having "ghost authorship" if individuals who wrote the trial protocol, performed the statistical analyses, or wrote the manuscript were not listed as authors of the publication, as members of a study group or writing committee, or in an acknowledgment. After examining 44 industry-initiated trials, the authors did not find any trial protocol or publication that explicitly stated that the clinical study report or the manuscript was to be written by the clinical investigators; none of the protocols stated that clinical investigators were to be involved with data analysis. They found evidence of ghost authorship in 33 trials (75%; 95% confidence interval 60%–87%). The prevalence of ghost authorship increased to 91% (40 of 44 articles; 95% confidence interval 78%–98%) when the authors included cases where a person qualifying for authorship was acknowledged, rather than appearing as an author. In 31 trials, the identified ghost authors were statisticians. Although most industry trials they reviewed had ghost authors, they acknowledge that the investigators probably overlooked some ghost authors, because they had very limited information to identify the possible omission of other individuals who would have qualified as authors. They concluded that *ghost authorship in industry-initiated trials is very common. Its prevalence could be considerably reduced and transparency improved if existing guidelines were followed and if protocols were publicly available*.

NIMH Collaborative HIV/STD Prevention Trial Group. Ethical issues in the NIMH Collaborative HIV/STD Prevention Trial. *AIDS* 2007;21 Suppl 2:S69–80.

This paper describes the development of decision rules regarding key ethical dimensions of scientific protocols for the National Institute for Mental Health (NIMH) Collaborative HIV/STD Prevention Trial, taking place in five countries (China, India,

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Peru, Russia, and Zimbabwe). The countries involved in this study have HIV rates from 0.1% to 27%. Their standard of medical treatment varies from access to antiretroviral drugs to no availability; reporting sexually transmitted diseases (STD) to government agencies is mandatory in some countries and not in others. The working group found that these variations presented challenges when developing decision rules that could be uniformly adopted across these countries and that simultaneously followed the ethical principles of beneficence, respect, and justice. The group used several strategies to identify and resolve ethical dilemmas for this international HIV prevention trial. First, they identified key principles, especially those derived for clinical therapeutic, biomedical preventive, or device trials. They convened a "workgroup on protecting human participants" to identify and implement optimal procedures for ensuring the ethical and equitable treatment of participants and to recommend methods to minimize physical, psychological, and social harm to the participants. Each trial site had a community advisory board, considered essential to identify local ethical issues and any possible resolutions to them. The NIMH established a data safety and monitoring board with ultimate responsibility for adjudicating ethical dilemmas and decisions. The protocols were deliberated thoroughly by the Trial steering committee, and approved by nine United States and five in-country institutional review boards. *The paper summarizes the decision rules adopted to resolve the identified ethical dilemmas. Especially important were the translation of clinical trial principles for a behavioral intervention trial, strategies for ensuring confidentiality and informed consent, dilemmas relating to partner notification of sexually transmitted infections (including HIV), minimizing the risks of social harm, establishing community partnerships, ensuring equity among United States and in-country principal investigators, and building capacity for additional research.*

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