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Administrative Staff Participation in Institutional Review Board Deliberations

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Most institutional review boards (IRBs) have support staff members who assist with the functions and operations of the IRB and the human research protection program (HRPP). Administrative staff are typically responsible for keeping meeting minutes and other IRB records; assisting with communications with investigators, institutions, sponsors and federal agencies; distributing copies of study protocols, consent forms, and other documents to the IRB; informing the IRB of regulations, standard operating procedures (SOPs), or other guidance; developing educational programs for the IRB and investigators; and dealing with reports of unanticipated problems, non-compliance and adverse events (McGough 2002). A staff member might have more HRPP expertise than any IRB member. For example, they often have graduate degrees and/or professional certifications, such as Certified IRB Professional (CIP). To obtain CIP certification, applicants must pass a national exam on research design, the federal regulations, and IRB administration. To maintain certification, individuals must attend continuing educational activities or retake the national exam (Public Responsibility in Medicine and Research 2016).

In their empirical research on IRBs, Laura Stark (2012) and Robert Klitzman (2015) both observed that staff members often make substantive contributions to the deliberations of these committees. Staff members often participate in discussions about risks and benefits, study design, informed consent, and regulatory compliance (Stark 2012, Klitzman 2015). Stark and Klitzman did not assess the influence that staff members have on IRB deliberations, but the fact that they do participate raises important issues concerning the review and oversight of research involving human participants. Should staff members participate in IRB deliberations? If so, how should they participate? This article will address these questions.

The federal research regulations include provisions concerning IRB membership, functions, operations, record-keeping, problem reporting and review of research, but they do not provide specific guidance concerning IRB support staff (Department of Health and Human Services 2009). However, one could argue the regulations imply a role for support staff, since the IRB might need assistance with record-keeping activities, communications with investigators, reporting of problems, policy development, and so on.

So, what role should staff play in the review and oversight of research? Before considering this question, it is important to note the regulations do not prohibit staff from serving as IRB members. If a staff person also has an appointment as an IRB member, then he or she could perform two roles: IRB member and administrator. This arrangement would raise no special problems concerning the review and oversight of research, provided the person can handle these different roles.

However, if a staff member does not have an appointment as an IRB member, his or her involvement in IRB decision-making could raise ethical and legal concerns, since the regulations do not explicitly authorize non-IRB members to participate in the review of research. While permitting staff members to vote would be a clear violation of the regulations, allowing them to influence deliberations could be problematic. One could argue that allowing IRB staff members to substantially influence IRB decisions would violate the spirit, if not the letter, of the law. Imagine, for example, how a very experienced and forceful HRPP executive might interact with a less-experienced IRB. The IRB's SOPs should

therefore draw a line between permissible and impermissible contributions by staff members. The SOP should take into account both the nature of the contribution (i.e., informational vs. substantive) and the perceived authority of the person making the contribution.

IRB professionals who are not IRB members should provide administrative assistance and support to the IRB but should not participate substantively in IRB deliberations, unless they are contributing to the discussion by providing the IRB with pertinent information, for example, about regulations or SOPs. IRB staff members could share information and documentation with the committee but should not offer opinions or advice concerning risk minimization, risk/benefit assessment, informed consent, or other substantive issues that affect IRB decisions.

The trouble with viewing the role of IRB staff members as purely administrative is that there is a continuum from providing facts, to explaining them, to interpreting them in context, to making judgments, and it is often not easy to distinguish between administrative and substantive interchanges with the IRB. (The same issue applies to expert consultants that an IRB might bring in for advice.) For example, suppose an IRB is discussing the risks of a proposed pediatric study and a staff member provides the committee with information about federal regulations concerning approval of pediatric research and the definition of minimal risk. It could be difficult for the staff member to provide regulatory information to the IRB without also engaging in a substantive discussion of how to interpret the regulations and apply them to this particular research proposal. Or suppose an IRB is reviewing a quality assurance officer's report of protocol deviations detected during an audit of a study, and that an IRB staff member provides additional information to the IRB related to its review of the study, such as previous protocol deviations, the investigator's behavior, and so on. Again, it would be difficult for the staff member to share this information with the IRB without also taking part in a substantive discussion with the committee concerning its decisions pertaining to the study, such as corrective actions or reports to federal agencies.

Although it is not realistic to think that staff members can and should play a purely administrative role on the IRB, staff members should take great care when engaging the IRB in discussions of substantive issues, so they do not usurp the IRB's authority. They should keep in mind that their primary duty is to provide administrative support to the IRB, not to influence IRB deliberations. They should strive to maintain neutrality when they provide the IRB with information, while recognizing they may engage IRB members in discussions of substantive issues. IRB SOPs should clearly describe the role of administrative staff in the review and oversight of research.

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References

Department of Health and Human Services. 2009. Protection of Human Subjects, Title 45, Part 46.

Klitzman RL. 2015. The Ethics Police? The Struggle to Make Human Research Safe. New York: Oxford University Press.

McGough H. 2002. Support staff. In: Amdur R, Bankert E (eds.). Institutional Review Board: Management and Function. Sudbury, MA: Jones and Bartlett, pp. 58-65.

Public Responsibility in Medicine and Research. 2016. Certified IRB Professional. Available at: http://www.primr.org/Subpage.aspx?id=1574. Accessed: January 20, 2016.

Stark L. 2012. Behind Closed Doors: IRBs and the Making of Ethical Research. Chicago: University of Chicago Press.

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