IRB Authority

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Dear Practical Ethicist,

On my review board, we sometimes mandate that non-compliant investigators not publish, or actually destroy, their data. We also on occasion ban investigators from conducting human research. However, I hear of IRBs getting sued for taking such actions. What actions should IRBs take when there is investigator non-compliance?

Signed,

What Should the IRB Do?

Dear WSIRBD,

Many IRBs have taken actions against non-compliant investigators, such as barring data publication, requiring data destruction, banning involvement in human research, placing written reprimands in personnel files, or mandating attendance at IRB meetings. IRBs occasionally have been sued for these types of actions.[1,2] These examples raise important questions about the authority of the IRB versus the role of the institution.

Most ethical and regulatory standards grant IRBs the authorities (a) to approve, require modifications in to secure approval, or disapprove research; (b) to observe or have a third party observe the consent process and the research; and (c) to suspend or terminate approval of research. These authorities focus the IRB on proposed or ongoing research. They do not focus on the behavior of individual investigators, which ought to be the realm of the institution.

Actions on proposed or ongoing research may involve the behavior of individuals, but the focus remains on the research. When investigators are not qualified to conduct proposed research, the IRB can disapprove the research or require changes to secure approval. When questions arise about the conduct of ongoing research, the IRB can observe or have a third party observe the research, including obtaining information from other sources. When investigators are non-compliant, the IRB can suspend or terminate the research. These actions are on proposed or ongoing research.

When there is no proposed or ongoing research for the IRB to review, sequestration of data, destruction of data, training, mandatory IRB service, debarment, and punishments represent general actions against investigators. They may change behavior for future research not yet presented to the IRB, but they fail to correct violations of rights and welfare experienced by victims of non-compliant research.

IRBs are on safe ground when taking actions against research consistent with the authorities listed above. However, institutions and IRBs should take care before exercising additional authorities. Taking actions inconsistent with written procedures can lead to allegations of arbitrary treatment. Actions to sequester or destroy data may conflict with the retention requirements of funding agencies, regulatory authorities, or legal agreements. Actions against an individual investigator to prevent participation in research may violate human resources procedures. When IRB members judge persons above them in the institutional hierarchy, the level of conflict and discomfort is palpably obvious to neutral observers, especially when those superiors are department chairs or other senior managers.

Institutions and IRBs encounter situations where investigators legitimately require behavioral changes before conducting future research. Although institutions can delegate this authority to the IRB, this is a role better assigned to management. Whereas the IRB's role is to protect subjects and oversee research, management's role is to oversee people and their behavior. Management, not the IRB, should implement the difficult actions required to alter adverse investigator behavior. There is a different dynamic when a dean issues a stern warning to the director of the cancer center, than when the IRB issues the same warning.

We often hear institutions claim that they are under a moral obligation to sequester or destroy the results of non-compliant research, because of the ethical consensus that publishing the results of unethical research is always wrong. However, this is an open debate among ethical scholars. When a leading journal published the results of the Nazi hypothermia experiments (Berger, 1990), some ethical scholars lauded the action as providing some meaning to those who suffered and died under Nazi persecution (Angell, 1990) while others decried the action as a violation of human rights (Correspondence: Nazi Science, 1991).

In summary, IRBs have the authority to approve, modify, disapprove, observe, suspend, or terminate research. Unless granted by the institution in a manner consistent with written procedures, they have no authority to take actions against people unrelated to a specific research protocol. In effective human research protection programs, IRBs should focus on how to protect human subjects in an individual study while institutions should manage people and their behavior. This dichotomy maintains the IRB as the protector and facilitator, and management as the enforcer of policy.

P. Ethicist

Notes

1. See http://www.courthousenews.com/2014/07/16/69539.htm.
2. See http://www.institutionalreviewblog.com/2011/03/professor-sues-brown-university-over.html.

References

Angell, M. (1990). The Nazi hypothermia experiments and unethical research today. *New England Journal of Medicine*, *322*, 1462-1464.

Berger, R. J. (1990). Nazi science—The Dachau hypothermia experiments. *New England Journal of Medicine*, *322*, 1435-1440.

Correspondence: Nazi Science. (1991). *New England Journal of Medicine*, *324*, 845-847.

Author Biographies

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