

Institutional Officials and the Price of Compliance

By Suzanne M. Rivera and Lois Brako

The U.S. Department of Health and Human Services (HHS) defines the role of the Institutional Official (IO) as the individual who is legally authorized to act for the institution with regard to oversight of its human research protection program (HRPP). The IO is responsible for ensuring that the HRPP functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects.

According to HHS, the IO should be an individual of sufficient rank and authority to ensure that the HRPP carries out all of its obligations effectively and efficiently. At most universities, the IO is a Vice President or Vice Chancellor for Research, although occasionally this responsibility is held by a Provost or a President. If the IO is not a faculty member with tenure, serious noncompliance can result in termination of employment. Because of the seriousness of their responsibilities, the IO is sometimes referred to as the "go to jail" guy or gal.

The IO is the public face of human research for a research institution. IOs also have numerous administrative obligations, including appointment of institutional review board (IRB) members and chair(s); allocation of budget and space to the IRB office; correspondence with OHRP, FDA, clinical affiliates, and study sponsors; and signing of authorization agreements with external IRBs. The IO sets the tone for the campus community with regard to compliance culture. He or she enforces the rules and can impose penalties for noncompliance.

Some IOs delegate certain responsibilities to a "right hand" designee. Often, this person (e.g., an associate VP, compliance officer, or IRB director) serves as the "eyes and ears" of the IO and files government paperwork on behalf of the IO. Common delegated tasks include maintaining and monitoring the FWA and DOD assurance, managing correspondence with federal agencies and offices (e.g., OHRP, FDA, DOD), managing accreditation activities and the QA/QI program, and helping to resolve IRB concerns (e.g., non-compliance, subject complaints, security breaches). Specific delegations should be documented.

Crisis Response

When an HRPP is functioning well, the IO may not spend much time on administrative duties. But, in the event of significant non-compliance or other research crisis, his or her leadership and meaningful involvement is essential. Examples of such events would be a security breach resulting in loss of HIPAA-protected data, investigator misconduct, serious injury of a study participant, receipt of a warning letter after an FDA inspection, or a natural disaster. Consequences for the institution might include the freezing or termination of approved protocols, suspension of a Federalwide Assurance, loss of AAHRPP accreditation, litigation and damaging media coverage.

Even very reputable research institutions have experienced major problems with investigator misconduct or serious honest errors that have resulted in high-profile examinations of their HRPPs. One infamous case involved a large academic medical center that had performed scores of unauthorized clinical trials, which resulted in an on-site OHRP inspection, a formal investigation into alleged scientific misconduct, criminal and civil lawsuits, and significant negative media coverage. In another unfortunate case at a different

academic medical center, a participant in a psychiatric clinical study committed suicide during a pre-study washout period. While a wrongful death lawsuit against the university was dismissed by the court, significant nationwide media coverage of the incident caused incalculable reputational harm.

What can be learned from such events? To start with, the IO's first priority is to address immediate concerns about the safety of human subjects. The IO must swiftly decide whether to suspend protocols, temporarily close laboratories, and/or sequester evidence. It also is important for the IO to assure institutional employees, students and the local community that the institution is giving the problem its full attention.

Once the immediate safety issues have been addressed, the IO should quickly assemble a crisis recovery team and empower the group to act. Likely members of the team include the IO's designee, the IRB Director/Manager, legal counsel, risk management, media relations, and any other parties that need to be involved to address the issues. If the IO is unprepared, unavailable or unwilling to lead the response team, the institution must identify a surrogate close to the IO who can take swift and decisive action.

The IO (or designee) should appoint one or more spokespersons to handle communications with the media and the public, so constant media queries do not distract the recovery team from other priorities. In the medium term, it is essential to develop a communication strategy for both internal and external messages. Communications staff should prepare statements for release to the media and institutional personnel, and answers to likely questions about the incident. Important communications should come from the top, i.e., the IO or the institution's leader. The response team should make sure others know to refer questions to the spokesperson(s).

In the medium term, the recovery team should start determining the root causes of the incident and identifying steps to prevent its recurrence. It may be necessary at this stage to include "street level" personnel who can explain how things really work. Brutal honesty is essential. Identify problematic processes, but do not turn the root-cause analysis into a blame-fest. The response team needs cooperation from everyone holding a piece of the puzzle.

A crisis might create an opportunity to do things that could not be done otherwise. Avoid the urge to quickly throw a little money at surface issues. This is an opportunity to get attention and resources to solve deeper problems. Remediation and improvement might require substantial time, money and effort.

Another important function of the response team is to develop a plan for repairing any damage to the institution's reputation. Trust is hard to build and easy to lose. The institution must accept responsibility for the incident, even if it, too, was duped or victimized. Commit to improvements, and keep personnel and the community informed about progress. Publicize successes. Share lessons learned with other institutions. Periodically re-assess plans. Fresh and objective eyes, in the form of an external review, can be helpful.

Behaviors to avoid include failing to acknowledge the problem, actively denying the existence of the problem, or covering up the problem. Do not refuse to take responsibility, blame others, lie about corrective actions, or make surface corrections until the crisis passes and then return to problem behaviors.

It is much better to avoid a crisis than to respond to a crisis. An IO can take various steps to identify problems before they escalate. Ensure that the IO or designee is informed of all FDA and OHRP communications and pending site visits, as well as problematic communications from study sponsors.

Monitor the OHRP website for determination letters and conduct reviews to see if your institution has similar problems. Monitor the IRBForum (<http://www.irbforum.org>) for issues *du jour* and problems at other institutions. Build relationships with street-level research personnel, e.g., study coordinators, who will see emerging problems first.

Conclusion

An effective IO must be well informed about the operations of the HRPP, be available when needed, and be supportive of HRPP policies and processes. It is the IO's responsibility to provide appropriate and adequate resources to assure that the HRPP functions properly. The IO must champion a culture of compliance and be prepared to respond to difficult situations.

These are serious responsibilities. The IO must not allow himself or herself to be lulled into complacency during long, uneventful periods. The price of a healthy HRPP program is eternal vigilance.

Authors

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