

## All Stakeholders in Human Research Protection Would Benefit from a Cooperative Enterprise That Moves Forward Without Blame

# Transparency and Cooperation

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Americans love competition. Free enterprise embraces the notion that more competition is good for the consumer and business; describing the pharmaceutical research field as “highly competitive” gives a positive impression. However, it also is a direct cause of investigator, sponsor, human research protection program, and government error. We put Sisyphus to shame (and spend billions) in pushing against this system’s inherent tendencies, struggling to police integrity. The solution is simple, if not easy. The stakeholders in research—sponsor companies, researchers, and the general public—need to cooperate. By taking simple steps to increase transparency in research, we in human research protection programs (HRPPs) can support the cooperation that is needed to change the research field from a financially inefficient machine of mistrust into a comfortable vehicle to meet all stakeholders’ needs.

The problems with the current system are not unfamiliar, though completely misunderstood and have led to non-existent public trust. Contrary to current opinion, the FDA and OHRP, despite a boost to their budgets and staff, were never designed to be the first line of defense in subject research protection. Pharmaceutical companies are not training grounds for avarice and their executives do not hang their morals on a peg outside of the boardroom. They do provide treatments we all desperately need. Researchers, also known as caring and compassionate people who believe

cures are out there to be found, deserve our support, not a watchful eye.

Despite the publicity of a GAO sting, HRPPs are made of diligent, hard-working people who balance, juggle, and perform contortionist routines to apply ethereal theory to messy and complicated real-world ethics. We are all aware of the problems of the system, but blame and punishment can never correct them. The real problem is not that there are a few bad apples in the barrel, but keeping apples crammed in a dark barrel in the first place.

The currently proposed quick-fixes to the current system, such as separating the FDA into drugs/devices and the rest of its responsibilities, do not address the underlying systemic issues. Any system that has competition at its foundation is doomed to fail, and there is a plethora of evidence that proves competition encourages inefficiency, duplicity, and scarcity, regardless of the performance of its components.

The transition from our current system to a cooperative one would require effort. A cooperative research enterprise would allow efforts to align, producing rapid, profitable, effective outcomes that cost less. Yet how can the stakeholders get from where they are to a cooperative system?

### Transparency in the HRPP

One way is through transparency. Anyone can trust when seeing what the other party is doing. Transparency, one of the new Obama-era buzzwords, appears to be a verb. The FDA just opened its black box, in a big-government sort of way, to produce “regulatory changes to improve

the FDA's ability to provide...useful and understandable information about FDA activities and decision-making to the public." Research institutions, such as Harvard, MIT, and 34 others have dedicated their published research as open-access and free on-line. PubMed does the same, and its connection to ClinicalTrials.gov imparts information as studies begin. Pharmaceutical companies are lining up to post their financial relationships for all to see. What could HRPPs do to be transparent, to facilitate cooperation?

While it may appear that OHRP registration could fulfill part of this, the process does not mean that the registered HRPP is compliant with regulation, that their written procedures have been vetted or there is any review of what is actually being done to protect research subjects and their information. Having significantly raised the standard, AAHRPP is a vanguard for a transparent system.

What else could a transparent, cooperative system entail? HRPPs could have something like WikiSOPs, modified for use at an individual site, but templates built in cooperation, transparent for all involved. Individual HRPPs could be "audited" in real-time by their peers and stakeholders; and as every HRPP and stakeholder would be able to contribute and cooperate, there would not be any big surprises to anyone. Best practices could be common practice. Regular self-reporting, similar to Australian ethics boards' annual reports, could be hosted by ClinicalTrials.gov or something similar and provide benchmarking data for transparent, cooperative quality improvement for research oversight programs. Of course, financial, commercial, affiliate, even preferential disclosures by stakeholders would allow HRPPs to become independent, objective managers of stakeholders' conflicting interests.

## **Cooperation is the Future of Research**

While current financial incentives are available for comparative research, going beyond that to collaborative research would provide the stakeholders the ability to meet each of their needs most effectively. The chemical cooperation required to combat HIV defenestrated old treatment paradigms, and is starting to do the same for old, insular concepts of treatment research and notions of industry cooperation in those concepts.

Research is our most powerful tool to produce objective evidence to answer real questions. Each of the stakeholders in research wants the same thing—to know

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the answers to those questions. We, the HRPPs, have a unique opportunity, as we were created to meld the perspectives of the medical research system.

HRPPs were created, not only to protect research subjects, but also to protect research from losing the perspective of its necessary support and responsibility, the society that allows it to continue. We, therefore, could continue to be champions of cooperation, leading by example. We ideally would demonstrate that we cannot only work together, but unite as facilitators in having research produce the ends to benefit all stakeholders.

The future of research is a positive and cooperative one. The only question is will it be a joyous transition, or one that has people fighting the whole way to a better place. Join with others who are making a change for the better; grasp the hand of an HRPP. As a wise and kindly revolutionary put it, become the change you want to see.

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