



Novel Approaches to Post-Approval Monitoring of Human Research in Developing Countries



Institutional Challenges

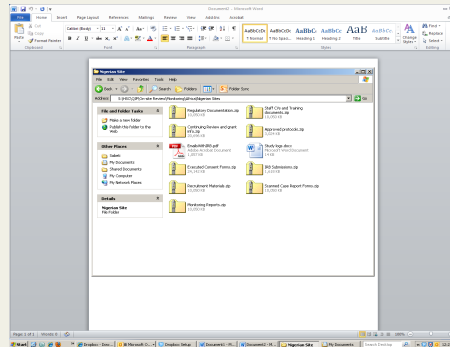
At HSPH, there is a large portfolio of complex transnational human research involving vulnerable populations; however, conducting post-approval monitoring is not feasible nor affordable for every study.

Study Site Challenges

- Internet accessibility and connectivity
- Maintaining records electronically
- Complying with data security provisions
- Managing multiple time zones

Approaches

1. Interactive video and audio chat
 - Skype
 - Facetime (iPhone to iPhone, iPad, iPod touch, Mac, or PC)
 - Google chat (Gmail, Google+, iGoogle, orkut, or Android OS device)
2. Education training/webinar platforms
 - WebEx (www.webex.com/)
 - Go To Meeting (www.gotomeeting.com)
3. Secure file sharing applications



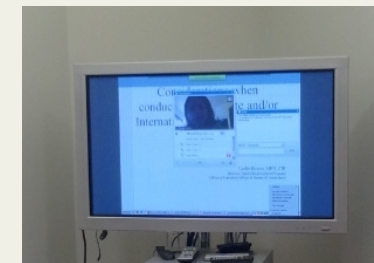
Dropbox screenshot of regulatory documentation and participant file information provided to the Quality Improvement Program by an investigator conducting research in Nigeria. Remote review conducted in Boston, USA in October 2011.

Harvard School of Public Health (HSPH)
Office of Regulatory Affairs & Research Compliance
90 Smith Street, Suite 335, Boston MA 02120

Presenters: Leslie Howes, MPH and Delia Wolf, MD, JD, MSCI

Conclusion

These approaches provide frequent and real-time review to study sites where on-site review would not otherwise be possible. Monitors are able to identify actual and/or potential protocol deviations and record keeping deficiencies, and provide adequate guidance on corrective actions and/or best practice recommendations.



Web-based conference hosted at HSPH in April 2012 entitled "Considerations for Conducting Multi-site International Human Research." Attendees participated from Boston, USA (pictured on left); China; Costa Rica (pictured on right); India; Kenya; Kuwait; Mexico; Nigeria, and Tanzania.

File Sharing Applications	Maximum File Size	Registration Required	Premium Account	Password Protected	Website
Pando	1GB	Yes	Yes	Yes	http://pando.com/
Wikisend	100Mb	No	No	Yes	http://wikisend.com/
SendThisFile	Unlimited	Yes	Yes	Yes	http://www.sendthisfile.com/
Dropbox	Unlimited	Yes	Yes	Yes	https://www.dropbox.com/
Box	Unlimited	Yes	Yes	Yes	http://www.box.com/

Solution

The Office of Regulatory Affairs & Research Compliance Quality Improvement Program has developed and implemented effective approaches to remotely conduct its post-approval monitoring.