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

<table>
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<tr>
<th>File Sharing Applications</th>
<th>Maximum File Size</th>
<th>Registration Required</th>
<th>Premium Account</th>
<th>Password Protected</th>
<th>Website</th>
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**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.

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