Investigator Expectations

- Efficient IRB administrative processing
- Timely IRB protocol review
- Rapid contract negotiations and execution

Administrative Limitations

- Limited personnel
- Protocol volume
Who Benefits from Rapid Processing

- Investigator
- Sponsors (NIH and Commercial)
- Community

Consequences of Slow/Inefficient Processing

- Investigator unable to conduct study in a timely fashion
  - Low enrollment or lack of enrollment
  - NIH/Federal Sponsor – Failed competitive renewals
  - Commercial Sponsor – Contract cancellation/failure to contract for additional studies
- Institutional consequences
  - Loss of direct and indirect funds
  - Loss of prestige
  - Failure to serve potential research volunteers in their community

Phase I IRB

- Identical protocol summary forms, consent form, policies, and procedures
- Fully constituted as other IRBs
- Meet virtually
- Submission two weeks prior to review
- Prior meeting minutes and protocol paperwork posted the week of review online
Phase I IRB
- IRB review process includes all key components
- Voting by individualized voice vote
- Recusal for conflict of interest by “hanging up” and then calling back in
- IRB decisions returned to investigator within days, often same day
- Responses for protocols not requiring full board review usually addressed electronically leading to approval
- Tabled protocol responses assigned to next available weekly meeting.

Initial Experiences
- Phase I IRB Meetings
  - 2009: 38
  - 2010: 44
  - 2011: 42
  - 2012: 46

- New (Initial) Submissions to PH1 in:
  - 2009: 32
  - 2010: 34
  - 2011: 35
  - 2012: 35

Initial Experiences
- Submission Types/Closures in 2012
  - New (Initial): 35
  - Renewals: 72
  - Amendments: 527
  - Administrative Closures: 23

- Timeliness of Review (2012)
  - Protocol Receipt by IRB till IRB Review (Average Application to Meeting Days): 12
  - Initial IRB review till IRB Approval (Average Meeting Date to First Approval): 12
  - Protocol Receipt by IRB till IRB Approval (Average Application to First Approval Days): 24