Children’s Hospital of Philadelphia: Recent Changes

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Chair,
Committees for the Protection of Human Subjects (IRB)

Recent Changes in CHOP IRB Procedures

- Unchecked the box 2012
  - Expanded Expedited and Exempt categories
  - 3 year approval of Expedited studies
- Change in IRB structure
- Development of totally electronic IRB reviewer form in eIRB (Click)
- Expansion of IRB Reliance Agreements

Problem: Too many members, too few MDs, too few qualified reviewers

- FY 2012
  - 3 IRBs + Rapid Action IRB
  - Hard to get enough MDs to a meeting
  - Many reviewers inexperienced clinical researchers
  - Responses to stipulations reviewed by same IRB
- FY 2013
  - 1 IRB + Rapid Action IRB
CHOP IRB Revised Structure

Prior IRB Structure  Post 2013 IRB Structure

FY 2012
- 3 IRBs – 17 members, 8 or 9 MDs
- Each IRB met monthly – 3 total meetings

FY 2013
- 1 IRB – 11 members with 11 alternates
- Meets 2x per month

* Originally an executive IRB, currently Rapid-Action IRB

Post-2013 IRB A Structure

- 11 members – each with an alternate
  - member + alternate minimum: 20 of 24 meetings
  - 10% salary support
  - Unaffiliated members receive fixed stipend
  - 2 unaffiliated members (green)

IRB D: Rapid Action IRB

- No change in IRB D
- 5 members
  - all members of IRB A
- Meets only as needed
  - 4 – 6 times/year for Emergencies
  - Urgent protocols
  - Decompress crowded agenda
Integrating Reviewer Comments into eIRB (Click Commerce)

- Built in capability: Reviewer comments - embed on a smartform page or document attachment
  - Smartform comments relate to a page of the application (little value to CHOP IRB)
  - Attachments involve use of MS Word forms
- Programmers developed a “project type” to create a reviewer form

Reviewer Form

Type of Reviewer Form Depends on Submission Type
Reviewer Form Covers all Required Determinations

2.0 Criteria for Approval under 45 CFR 46.111(b) or 21 CFR 50 and CHOP Research Policies

Present Title: Short-term Outcomes of Interventions for Reproductive Dysynchrony: Study 1 and 2

1.0 The role in subjects minimized by using sound research design.
   - Yes
   - No
   - Clear

2.0 Subjects are not consistently exposed to risk.
   - Yes
   - No
   - Clear

3.0 When research procedures, procedures are combined with those already being performed for diagnostic or treatment purposes.
   - Yes
   - No
   - NA
   - Clear

4.0 Refers to subjects as reasonable to realize anticipated benefits, if any, to subjects, and the importance of the knowledge that may or may not be gained.

5.0 Selection of subjects is equitable.
   - Yes
   - No
   - Clear

Comment Boxes are Interspersed

Children

10.4a Select the Subject categories that apply to this research. (Check all that apply)

- Healthy (46.414 or 50.01)
- Greater than 18mo less than 180 days old (46.414 or 50.02)
- Greater than 18mo less than 180 days old (46.414 or 50.03)
- Research not otherwise approved, which presents an opportunity to understand, prevent, or alleviate a serious medical condition affecting the health or welfare of minors (46.414 or 50.01)
- Not able to determine

10.1 Comments:

Q4.3 Although the multi-center protocol references recruiting potential subjects over the phone, CHOP will not engage in phone recruitment activities.

Required Modifications

- Stipulation section
  - protocol, consent form, application and other
- For full board studies stipulations pulled into meeting minutes and letter to investigator

27.9 Consent Stipulations

☐ The IRB has edited the consent form. Please review for edits to sections that are correct. Once final, please initial and clear.

☐ Changes addressed concerning consent (e.g., Section 13.2 using the signed consent letter). Please do not delete any documents or text here.
Motion

Designation of reviewer for investigators response

IRB Minutes

Remainder of minutes is the revised reviewer form with all determinations and comments

Approval Letter generated from final stipulations
IRB Reliance Agreements

- Longstanding agreements
- Recent and in process agreements
  - Utah (Pediatric Critical Care), CHB-CCHMC-CHOP
  - PEDSnet (in process)
- Requirements
  - Must assume full responsibilities – we will no longer enter into facilitated reviews
IRB Improvement Project
Michele D. Kipke, PhD, Vice Chair of Research

Targets for Intervention

1. Implement a Flexible IRB Model
2. Work with HSPP staff to streamline IRB pre-review and submission
3. Ongoing monitoring of performance indicators

New IRB Leadership:
1 Chair
7 Members
7 Vice Chairs

New IRB Flexible Model

1 Chair
7 Members
7 Vice Chairs

New IRB Leadership:
Alan Lewis, MD Chair
Rob Bart, MD Vice Chair
Girish Chail, MD Vice Chair
Jeff Gold, PhD Vice Chair
IRB Turn Around Time

IRB User Satisfaction (Feb-April 2014)

IRB/Regulatory Support Specialist

- IRB application preparation and submission
- Regulatory and compliance documentation and submission to study sponsors
- Education and training of study teams regarding regulatory issues
- Liaison between the study team and the IRB
The Issue with Full Board Review

- Turnaround Time
- Large agendas / Long meetings
- Large quorum requirements
- Long waits for re-review of tabled studies
- High volume of correspondence from IRB staff to investigators after monthly meeting
- Challenges IRB staff, investigators, and sponsors
WFSOM Background Cont.

• Each IRB meeting took several hours

• Food breaks helped to refocus attention

• Quorum was often hard to achieve
  – Members needed to be late
  – Members needed to leave early
  – Agenda was juggled to accommodate needs

• Best discussion of submissions seemed to occur in the first hour or so

The Idea for a Revised Process

• Examined the processes of highly efficient IRBs

• OHRP training video “Institutional Review Board (IRB) Membership”
  http://www.hhs.gov/ohrp/education/training/ded_video.html

• Ideal agenda size

• Times of day for meetings

New Process Proposal

• Greater number of Boards with more frequent meetings

• 10-12 members per board

• 4-6 agenda items

• Midday meetings so members can use lunch time
Our Analysis

• More than one meeting per month may be difficult to schedule
  – The shorter meetings should be easier to attend and take away less clinical time
• Smaller IRB panels may have inadequate expertise
  – Strategic assignment, use of alternates and consultants will eliminate this issue
• The workload may be overwhelming to IRB staff
  – Each week an analyst has only a few full board studies to handle
• Individual members may have to review more
  – Work is now spread between 16 meetings instead of 4

The Specific Changes

• Split each IRB panel into two (4 to 8)
• Rescheduled meetings so that each of the 8 panels meets every other week
  • Boards 1-4 meet one week
  • Boards 5-8 meet the next week
• Each month there are at least 16 IRB meetings

The Specific Changes Cont.

• Added members where necessary to each board
  – Some who left because of time conflict returned to try the new schedule
• Moved to a more convenient conference room with video & teleconferencing capabilities
  – We could use it now because of the smaller roster
• Assign Studies Strategically to the correct Board with appropriate expertise
Outcomes


• IRB-Only Time
  • 46 days total before change
  • 21 days total afterwards (7 IRB + 14 investigator)

Outcomes Cont.

• IRB meetings last about an hour
• Tabled protocols can be reconsidered in two weeks
• IRB members can return to their clinic or office for afternoon appointments
• Post-meeting correspondence can be sent same-day
• Minutes for meetings can be written up much more quickly

Overall HRPP Turn-around Time
Outcomes Cont.

- IRB turnaround decreased 54%
- HRPP turnaround deceased 46%
- Discussion Time increased 33% per agenda item
- Smaller agendas increased the likelihood of thorough review of ALL submissions by ALL IRB members, not just primary reviewers

IRB Member Reaction 2012

As a member of the Wake Forest School of Medicine
IRB, I like the new 8 board structure.

Strongly Agree
Agree
Neither Agree nor Disagree
Disagree

IRB Member Reaction 2012 Cont.

I believe that since the 8 board model was adopted, the quality of discussion the IRB is able to have regarding each agenda item is:

- Significantly better
- Somewhat better
- Not changed
- Somewhat worse
- Significantly worse
IRB Member Reaction 2012  Cont.

With the new 8 board structure, I am more likely to be able to review all the agenda items, even those not assigned to me as a primary reviewer.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree

Sustainability

- July 2013 – February 2014
- Total HRPP turnaround 35 Days (15 HRPP / 20 Investigator)

Sustainability Cont.

2013 IRB Member Survey

- Please describe your thoughts on the current duration of IRB meetings.
  - Too Short
  - About Right  100%
  - Too Long
  - No opinion
Sustainability Cont.

2013 IRB Member Survey

• Please describe your thoughts on the time reviewers spend discussing protocols.
  – Too Short
  – About Right 100%
  – Too Long
  – No opinion

• indicate the percentage of scheduled board meetings that you attended within the past year.
  – 0-25%
  – 26-50% 3%
  – 51-75% 97%
  – 76-100%