

# Flexibility Coalition Conference Call

June 12, 2014

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**Host:** Susan L. Rose, Executive Director, Office for the Protection of Research Subjects,  
University of Southern California

## **Speakers**

- Mark Schreiner, IRB Chair, Children's Hospital of Philadelphia (CHOP)
- Michele Kipke, Vice Chair of Research, Department of Pediatrics, Children's Hospital Los Angeles (CHLA)
- Joseph Andrews, IRB Director, Wake Forest School of Medicine

## **Susan Rose – Welcome**

More than 54 participants have dialed into the call

We will share:

- call slides and notes
- article regarding Mike Carome of Public Citizen and the SUPPORT trial
- [Info about CTTI](#) (public-private partnership to identify and promote quality and efficiency of clinical trials)
- Letter to Jerry Menikoff offering examples from Flexibility Coalition for NPRM

## **Mark Schreiner – Children's Hospital of Philadelphia**

Children's Hospital of Philadelphia unchecked the box in 2011, expanded the categories of expedited and exempt research, and instituted a policy for 3-year approval for non-federally funded research.

Further innovations were still needed: CHOP reviews 600 new studies per year and IRB turnaround time lagged. The best reviewers were too busy to attend IRB meetings and there were few reliable scientific reviewers to be had.

Starting in 2013 (July 1), CHOP began restructuring their IRBs and e-system: They moved from having 3 IRBs and 1 "rapid action IRB" to having 1 regular IRB and 1 rapid IRB; from having 17 members per committee plus alternates (60 people total) to 1 committee with 11 members and 11 alternates. They meet for two meetings per month instead of 3.

Now, each member is paired with an alternate. 90% of meetings must be attended by either the member or the alternate. All members are paid 10% of their salary to conduct what amounts to 2 work-days per month. Duration of meetings has not increased. CHOP has seen a huge increase in quality of membership.

The "rapid action IRB" is composed of 5 members who meet as needed (4-6 times per year) to address study events requiring immediate review, urgent protocols, or decompress crowded agenda.

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Changes to the e-system (Click Commerce) now allow CHOP to attach reviewer notes to protocols and embeds reviewer notes in each section of the IRB application. A reviewer form (checklist) was also created in the system which displays all the regulatory criteria so that the reviewer can confirm each requirement has been satisfied and each IRB determination can easily be transferred to meeting minutes and IRB correspondence. CHOP has three longstanding Reliance Review arrangements (Penn, NCI and Utah for Pediatric Consortium). For these arrangements, CHOP requires that the IRB of record take full responsibility and there's a clear delineation of responsibilities/procedures.

## **Michele Kipke – Children's Hospital Los Angeles**

Children's Hospital Los Angeles conducted weekly IRB meetings (1 ½ hours long), at a rate of 6-7 protocols per meeting. They received many investigator complaints about slowness. CHLA looked at metrics from peer institutions, conducted benchmark self-evaluation, and discovered IRB approval at CHLA was taking twice as long as other children's hospitals. Time-to-approval for most expedited review studies was the same as full board studies. CHLA engaged Huron to improve program. HSPP staff were taking too long on pre-review beyond appropriate scope so a checklist was instituted to improve efficiency and focus the review on regulatory items. IRB staff pre-reviews now concentrate on identifying/triaging protocols that need the most time and work.

New approach: "Flexible IRB model". CHLA now has 4 boards composed of 7 standing members (1 chair, 3 vice chairs, pool of alternates). Alternates are used for their expertise as needed.

1 meeting per week / 4 meetings per month for 90 minutes (plus prep time), averaging 7 or more protocols per meeting. Committee member commitment is only once per month. Plan is to add a 5<sup>th</sup> meeting for months that have 5 weeks. Projects go to committee within 8 days of submission.

Now, staff are organized into pairs and assigned to facilitate committee meetings together. Goal was to get staff and IRB members on the same page. Minutes are worked on during the meeting and projected on screen for members to see. This helps ensure that communication to investigators is clear. By the end of an IRB meeting, staff should have minutes complete and know what follow-up will be taken with each protocol. One staff member has been reassigned to act solely as support for IRB members. Also, a new staff member was added who helps investigators with IRB submissions and other regulatory issues; mostly for fellows who have problems with submissions.

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Staff satisfaction has improved and so has faculty satisfaction.

In summary, CHLA has reduced turn-around times from more than 150 days to less than 65 days by implementing smaller IRBs, retraining staff, and getting proposals as clean as possible before meeting so that decisions happen quicker.

FYI -- CHLA and USC added button to their e-submission system which allows study staff to change the personnel listed on their protocol (except for the PI/Co-I) without having to submit a study-amendment for IRB review.

## **Joseph Andrews – Wake Forest School of Medicine**

Wake Forest IRB has a small administrative team to handle a workload of 2,400 protocols per year. They had 4 IRB panels of 18 regular members that convened for 8 meetings per month at a rate of 16-25 items per meeting. Meetings were long and quorum was hard to achieve.

Though IRB turn-around time at Wake Forest (46 days) fell within the national average, they decided to revise their process to improve efficiency.

They chose to have 8 IRB panels of 10-12 members to meet more frequently for shorter meetings (4-6 agenda items) – 16 meetings per month! The agendas are smaller and meetings run for 1 hour to 1.5 hrs.

Previously, studies were reviewed by the full board without requiring that all ancillary committees approve the study prior. Now, ancillary committees have been added to the electronic system so that when PI selects study academic department (eg. Cancer, Clinical Research Unit) the required ancillary committees get early notification so that they can begin their reviews early in the process.

Board members were very skeptical that it would work.

Staff love the new model because though they have a meeting every week, it is easier to prepare for the meeting and easier to wrap up. The model gives staff more stability in their monthly workload.

Wake Forest also took the additional step of installing a low-cost camera in the meeting room so that IRB members can attend any meetings via skype.

The result was a reduction of 46 days to 21 turn-around time by implementing changes that cost very little.

Once a protocol comes in, it is assigned to a meeting in 7 days' time and tabled protocols can be reconsidered in two weeks. Discussion time per protocol increased 33%.