

# IRB Transformation Without a Contractor

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## NS-LIJ Research Portfolio

Total number of active protocols: ~2000

NS-LIJ IRB:

Exempt Studies: 510

Expedited Studies: 840

Full Board Studies: 279

Protocols using an External IRB: 357

Biomedical Research: 90%

Socio-Behavioral Research: 10%

## Office of the HRPP Staff

9 total staff members:

- HRPP Director
- HRPP Assistant Director
- 4 Full-Time IRB Case Managers
- 1 Part-Time IRB Case Manager
- 2 IRB Coordinators

## Impetus for Change

1. AAHRPP Site Visit

2. “For One IRB, Splitting Up is Easy to Do”

IRB Advisor, July 1, 2013, Vol. 13, Issue 7, p82

## Old System

Four IRB rosters registered with OHRP, each listing 10-12 voting members, and their alternates.

Four IRB committees, each meeting once per month.

Two IRB committees designated for individual institutions, and two IRB committees designated for the health system generally.

Two IRB committees made up of site specific personnel, and two made up of employees from any site.

In person meetings.

IRB meetings attended by 20 to 30 persons.

IRB agendas set by public deadline date.

Long agendas, including 15+ items.

IRB Meeting length between 1 to 3 hours.

## New System

One IRB roster with OHRP, listing all IRB members, identifying 9 as primary and all others as alternates. (Separated operationally into 4 committees).

Four IRB committees, each meeting bi-weekly.

Four IRB committees all designated to be generalist committees, reviewing research from any health system site.

Four IRB committees made up of personnel from any health system site.

Virtual meetings via videoconference ( Zoom Cloud Meetings).

IRB meetings attended by 7 to 15 persons.

No submission deadlines; submissions assigned to the first available meeting, within 14 days of receipt.

IRB agendas limited to no more than 5-7 items.

IRB meeting time limited to 60 minutes.

## Workflow

Full Board item received in the Office of the HRPP



IRB Coordinator lists item on a shared spreadsheet for assignment to a meeting.



Every Monday and Wednesday, the Assistant Director assigns new studies to an IRB meeting that will take place within 14 days of receipt.

- PR's, MODS, Resubmissions, all go back to original reviewers.

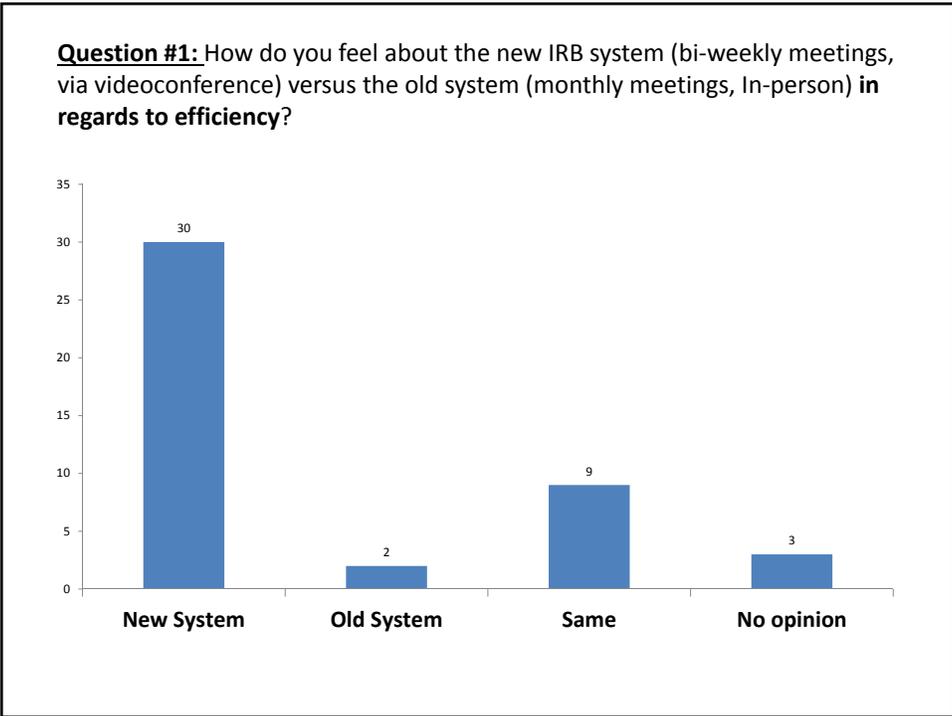


7 days before a meeting, the IRB Coordinator creates a one page Agenda document, and posts all items to review to a central website.

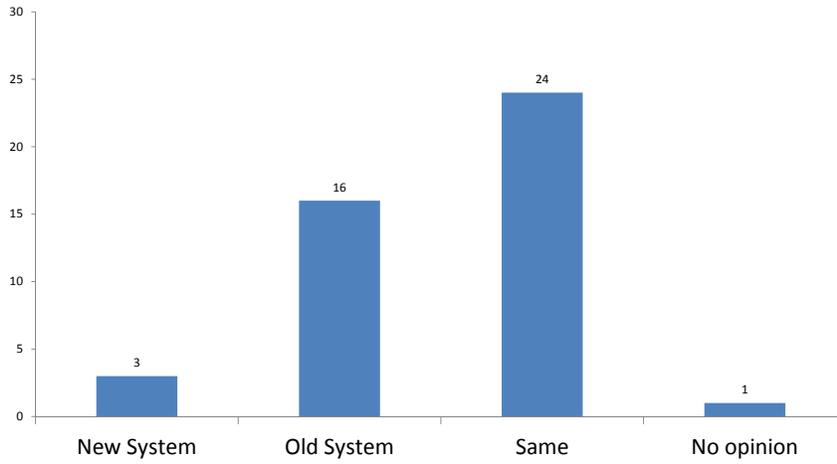
- They then e-mail the Committee and IRB staff notifying all of the agenda, and their assignments.

# IRB Member Feedback

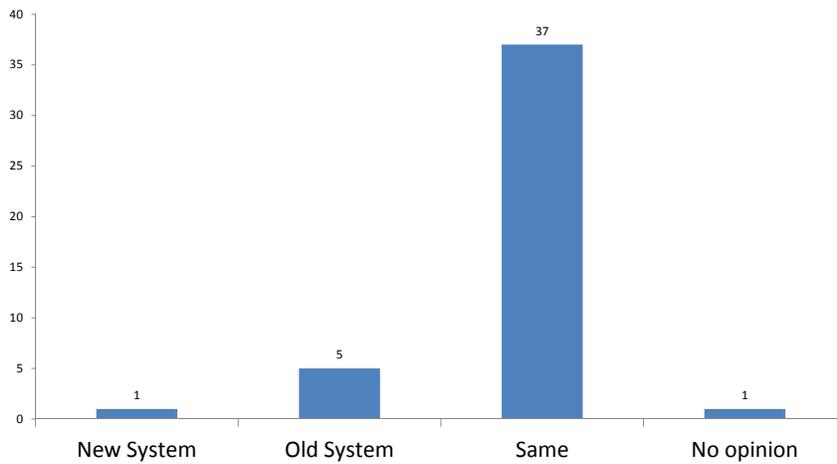
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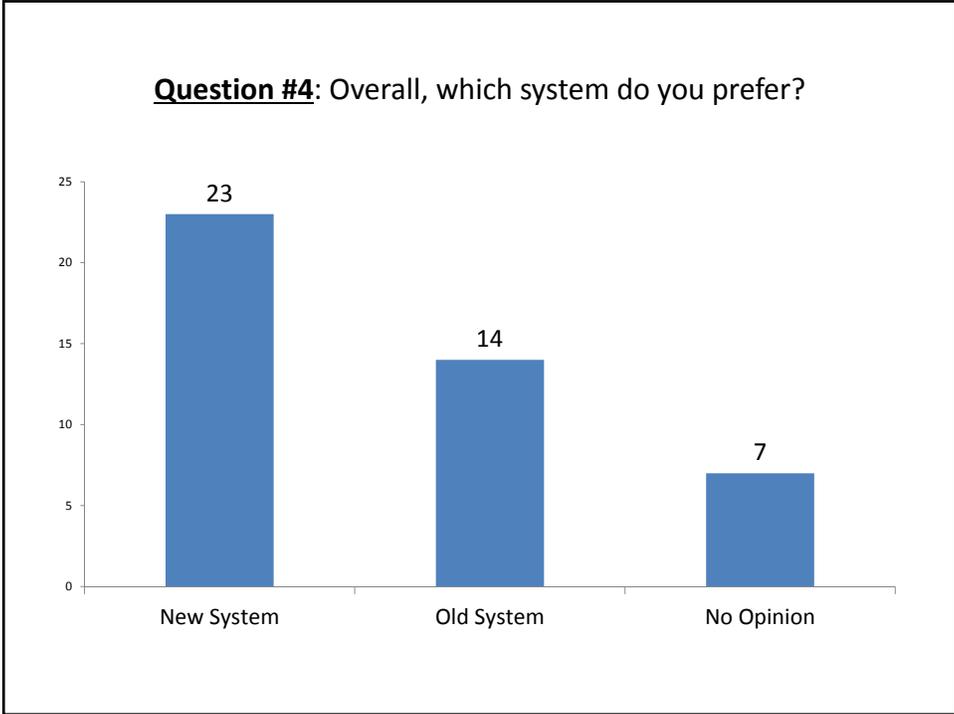


**Question #2:** How do you feel about the new IRB system versus the old system in regards to **opportunity for discussion**?



**Question #3:** How do you feel about the new IRB system versus the old IRB system in regards to **protection of human subjects**?



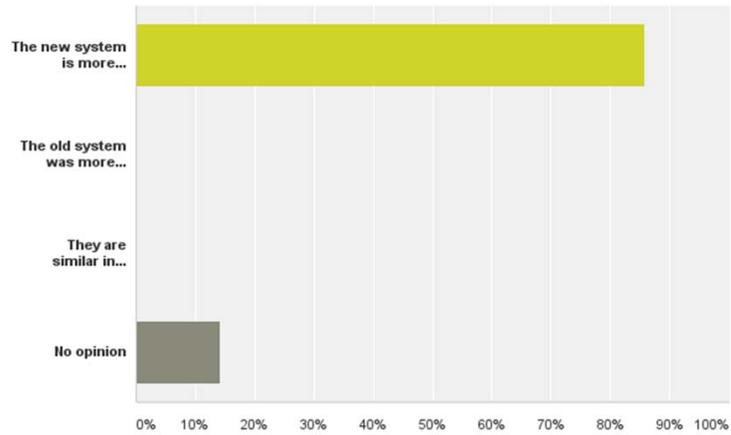


IRB Staff Feedback

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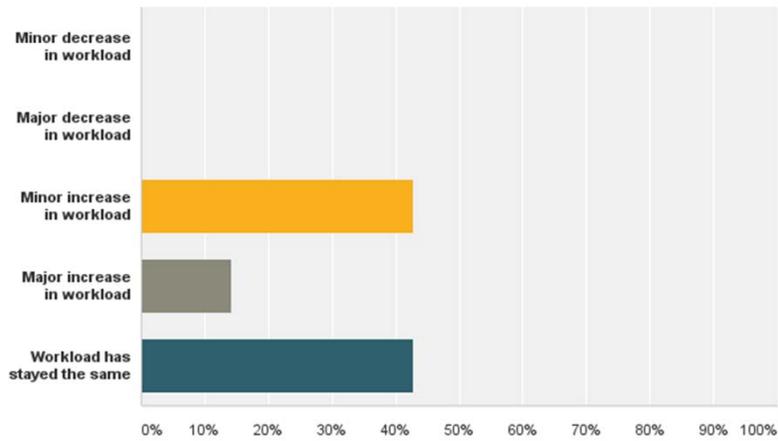
**Q1 How do you feel about the new IRB system (bi-weekly meetings, via videoconference) versus the old system (monthly meetings, In-person) in regards to efficiency?:**

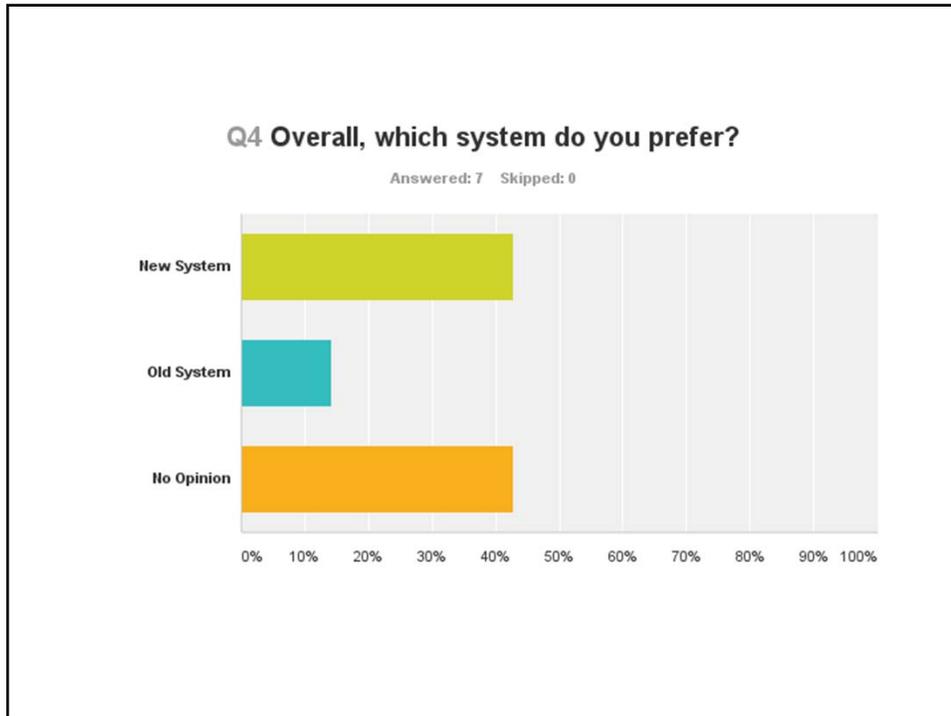
Answered: 7 Skipped: 0



**Q5 How has your overall workload been affected by the New IRB structure?**

Answered: 7 Skipped: 0





## Result – Overall Turnaround Times

**Overall Turnaround Time (OTT) for New Submissions has decreased by over 50% under the new system.**

OTT for Full Board Studies Received in 2013

(old system; n=67):

- Median: 98 Calendar Days
- Average: 114 Calendar Days

OTT for Full Board Studies Received from 9/1/2014 – 5/1/2015

(new system; n=34):

- Median: 44 Calendar Days (**Reduction: 55%**)
- Average: 53 Calendar Days (**Reduction: 54%**)

## Result – Overall Turnaround Times

### Why have times gone down?

1. Submissions go to a meeting much faster (between 7 and 14 days from submission).
2. Deferral responses go to a meeting much faster, as each committee meets every 2 weeks.
3. Investigators seem incentivized to respond within a week, so the response can go to the next IRB meeting.
4. IRB decision letters have to go out quickly, or else the staff person gets overrun by the next meeting.
5. We've instituted a number of changes that may also be reducing OTT.

## Benefits

1. Reduction in overall turnaround time.
2. Ad hoc meetings are easy to arrange.
3. Small agendas allow members to review/be familiar with each item, so less time spent discussing summaries of the protocol, and each member can find the 46.111 criteria.
4. IRB staff can join or drop off of meetings as needed, to cover their items.
5. Time savings by shifting to virtual meetings is incalculable.

## Costs

1. Scheduling items for full board review is more time consuming
  - Lots of variables to consider, lots of meetings to choose from.
2. Compiling meeting minutes, and distributing them to members, is more cumbersome.
3. Vote count can be more challenging in a full board meeting (who is voting, who is not?)
4. Less time for pre-review or to find consultants

## Final Thoughts

1. Be careful how you announce the change to researchers (or don't announce it). We notified the research community months in advance, and our first month under the new system was the heaviest in health system history.
2. Expect some members will not go along with the change.
3. Add more nonscientists/unaffiliated members to your roster.

Thank You

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