

## Flex IRB & Workflow Implementation with External Support

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Flex Coalition Luncheon  
AAHRPP Conference  
May 21, 2015



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## Flex Operational Changes

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- IRB staff role changes (generalist vs. specialist)
- IRB staffing structure (teams vs. individuals)
- IRB staff serving as designated reviewers
- Flex IRB model
  
- Other important areas of change:
  - No duplicate data entry or decision making
  - Focus on required regulatory documentation
  - Reduce IRB scope creep



## Workflow Examples

- IRB reviews are often divided by type of review and type of submission
- Many IRB offices develop workflows based on these types of reviews and submissions

Type of Review	Type of Submission
<ul style="list-style-type: none"> <li>• Full Board</li> <li>• Expedited</li> <li>• Exempt</li> <li>• Not Human Subjects Research</li> </ul>	<ul style="list-style-type: none"> <li>• Initial Review</li> <li>• Amendment</li> <li>• Continuing Review</li> <li>• Unanticipated Problems</li> </ul>

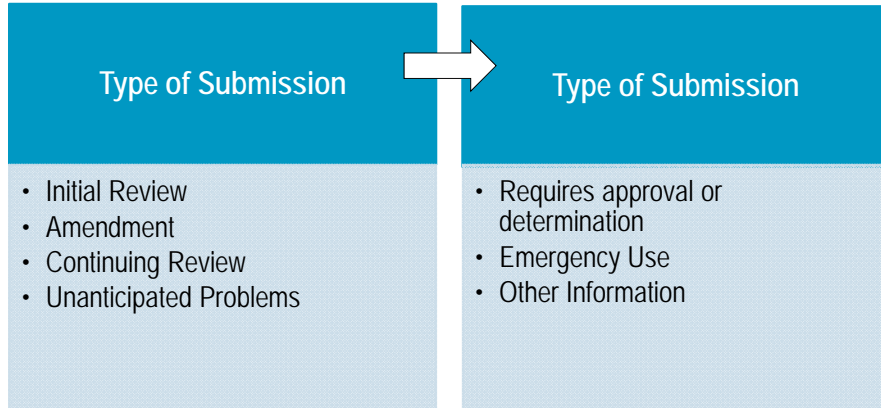
## IRB Staffing Example

- Staff responsibilities are then often assigned based on type of review and/or type of submission

IRB Analyst	<ul style="list-style-type: none"> <li>• All full Board reviews</li> </ul>
IRB Coordinator	<ul style="list-style-type: none"> <li>• All continuing reviews (full Board and expedited)</li> </ul>
IRB Administrator	<ul style="list-style-type: none"> <li>• Expedited amendments</li> </ul>

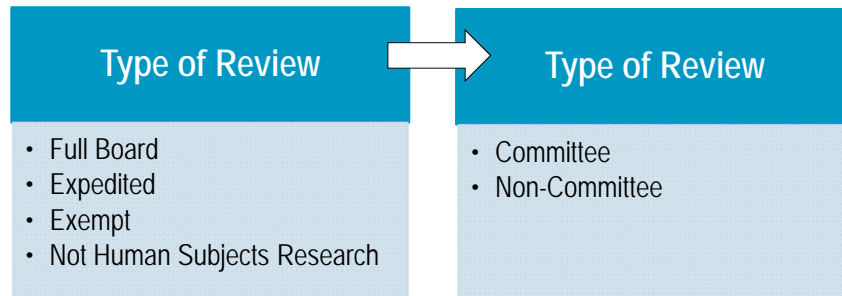
## Simplify Workflow and Restructure Office

- Can simplify processing by re-organizing submission types



## Simplify Workflow and Restructure Office

- Can simplify workflow by re-organizing type of review
- Each submission can then be routed through a workflow based on type of review



## Standard IRB Model vs. Flex IRB Model

	Standard Model	Flexible Model Example
Roster Size	15 Members	5 Members
Alternates	Limited	15 Alternates
Number of Members needed for Quorum	8	3 (combination of members and alternates)
# meetings members/ alternates attend per month	1	1
Number of IRB meetings per month	2	4
Materials to be reviewed per meeting	2 week's worth	1 week's worth

## Keys to Success of Flexible Model

- Leadership Support
- Scheduling
  - Need to have an efficient system which tracks which members/alternates are committing to attend which meetings
- Meeting management/flow
  - With a possibly changing group of meeting attendees all participants need to be prepared to contribute equally at meeting
  - Attendees need to be prepared to review all kinds of studies
- Minimum level of participation
  - Expectation needs to be set on how many meetings per year each member/alternate will attend

## Why Do Institutions Implement Flex Changes?

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- Increase efficiency
- Decrease unnecessary administrative burden
- Increase IRB membership
- Expand IRB expertise
- Implement scalable IRB structure to handle increased workload
- Implement a “paradigm shift” for their HRPP
- Reduce IRB scope creep

## Why Choose to Have External Support?

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- Implementation of flex IRB model is part of other operational changes
- Not enough internal resources
- Flex IRB change will be significant vs. current structure; need assistance with change management
- Purchase/use of external tools and systems
- Implementation experience at other institutions
- Better reception of change driven from outside group

## Example: CHLA IRB Before Flex IRB

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- Structure
  - One Chair and one Vice Chair
  - Twenty-two IRB members in attendance
  - Two meetings per month
- Turnaround times before implementation of the flexible model
  - Exempt = 11 days from submission to completion
  - Expedited = 38 days from submission to completion
  - Full Committee = 82 days from submission to completion

## Example: CHLA IRB After Flex IRB

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- No submission deadlines
- Structure
  - One Chair and three Vice Chairs
  - 5 regular members with many alternate members that can broaden needed expertise (membership pool)
  - 6-8 IRB members/alternates in attendance at each meeting (each person “assigned” to a meeting)
  - Four meetings per month (with the option of additional meetings as needed)

# Example: CHLA IRB Results

