Flex IRB & Workflow Implementation with External Support

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Madeleine Williams, MA, CIP
Senior Director
Huron Consulting Group
mwilliams@huronconsultinggroup.com
312-479-3374

Flex Operational Changes

• 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

<table>
<thead>
<tr>
<th>Type of Review</th>
<th>Type of Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Board</td>
<td>Initial Review</td>
</tr>
<tr>
<td>Expedited</td>
<td>Amendment</td>
</tr>
<tr>
<td>Exempt</td>
<td>Continuing Review</td>
</tr>
<tr>
<td>Not Human Subjects</td>
<td>Unanticipated Problems</td>
</tr>
</tbody>
</table>

IRB Staffing Example

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

- **IRB Analyst**
  - All full Board reviews

- **IRB Coordinator**
  - All continuing reviews (full Board and expedited)

- **IRB Administrator**
  - Expedited amendments
Simplify Workflow and Restructure Office

- Can simplify processing by re-organizing submission types

<table>
<thead>
<tr>
<th>Type of Submission</th>
<th>Type of Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Review</td>
<td>Requires approval or determination</td>
</tr>
<tr>
<td>Amendment</td>
<td>Emergency Use</td>
</tr>
<tr>
<td>Continuing Review</td>
<td>Other Information</td>
</tr>
<tr>
<td>Unanticipated Problems</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Type of Review</th>
<th>Type of Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Board</td>
<td>Committee</td>
</tr>
<tr>
<td>Expedited</td>
<td>Non-Committee</td>
</tr>
<tr>
<td>Exempt</td>
<td></td>
</tr>
<tr>
<td>Not Human Subjects Research</td>
<td></td>
</tr>
</tbody>
</table>
Standard IRB Model vs. Flex IRB Model

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

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?

- 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?

- 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

- 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

- 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

IRB Full Committee Turn Around Times (Quarterly)

Days to Approval

Studies Approved

First flexible IRB meeting

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