Reducing Adenoviral Patient Infected Days (RAPID) Study: Navigating Institutional Review Boards for a Multi-center Clinical Trial

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PURPOSE

• The RAPID study is a multi-center randomized trial assessing the efficacy of one time 5% ophthalmic Betadine for the treatment of adenoviral conjunctivitis.
• Our experience regarding the IRB approval process has highlighted areas to decrease the time between submission and IRB approval.
• Prolonged time for IRB approval results in delayed recruitment costing valuable time and the appearance of falling behind scheduled deadlines.
• This report identifies differences in the IRB approval process between sites, provides realistic timetables for future multi-site studies, and describes methods to expedite approval.

METHODS

• IRB approval was obtained for this report from the University of Illinois at Chicago.
• Principal investigators of participating RAPID sites including private and state colleges or universities, medical schools, a military hospital and an Indian Health Services center completed a survey to document their IRB approval process.
• One site was excluded that chose to discontinue participation prior to IRB approval.

RESULTS

<table>
<thead>
<tr>
<th>Site type (n=8)</th>
<th>8 Weeks 13%</th>
<th>4 Weeks 25%</th>
<th>3 Weeks 25%</th>
<th>1-2 Weeks 37%</th>
<th>12+ Weeks 38%</th>
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</thead>
<tbody>
<tr>
<td>University or Hospital based clinic</td>
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<tr>
<td>affiliated with a teaching hospital</td>
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<tr>
<td>University or Hospital based clinic</td>
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<tr>
<td>not affiliated with a teaching hospital</td>
<td>4* (50%)</td>
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<tr>
<td>Military Clinic</td>
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<td>Indian Health Services Center</td>
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Influencers of Initial and Final IRB Response Times

INFORMATION AND TRAINING

• CITI Training: 7 (87.5%)
• Institution-specific online courses: 6 (75%)
• Biosafety/environmental health safety: 1 (12.5%)

Informed consent: 100%
Protocol: 100%
Informed consent: 100%
Copies of recruitment materials: 100%
Verbal Scripts: 87.5%
HIPAA authorizations: 100%
Informed consent: 100%
Copies of all questionnaires: 75%
Copies of all survey instruments: 75%
Data collection forms: 75%
Initial review application: 62.5%
IRB approval from other institutions: 62.5%
Copy of federal grant: 62.5%
Separate use drug forms: 62.5%
Co-investigator and key personnel form: 62.5%
Consortium financial agreement form: 50%
Drug study registration form: 50%
Research using investigational drugs form: 50%
IND application: 37.5%
Biological use of tissues/sample bank form: 37.5%
Performance sites form: 37.5%
Data use agreement: 37.5%
Infection control form: 25%

DISCUSSION

All NIH studies require site personnel to complete ethics and safety training before protocols can be approved. Timely IRB approval is a hurdle for all investigators. Sites associated with university teaching hospitals may encounter longer times to approval. Lack of centralized IRB results in varying requirements between sites. Consultation with IRB staff prior to submission can reduce wasted time and effort and may aid in expediting the review process.

CONCLUSION

The IRB approval process is unique to each site, requires considerably more preparation than simply submitting a protocol, and can cause a significant delay in the start of clinical study. Allocating adequate time and resources and seeking IRB member assistance are vital steps in conducting clinical research.

SUPPORT

• DiaSorin Molecular LLC (Cypress, CA) for loaning the study a Liaison MDX instrument for qPCR analysis.
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• Clinical Trial Registration: # NCT02472223 https://clinicaltrials.gov/ct2/show/NCT02472223