Board # 89

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.

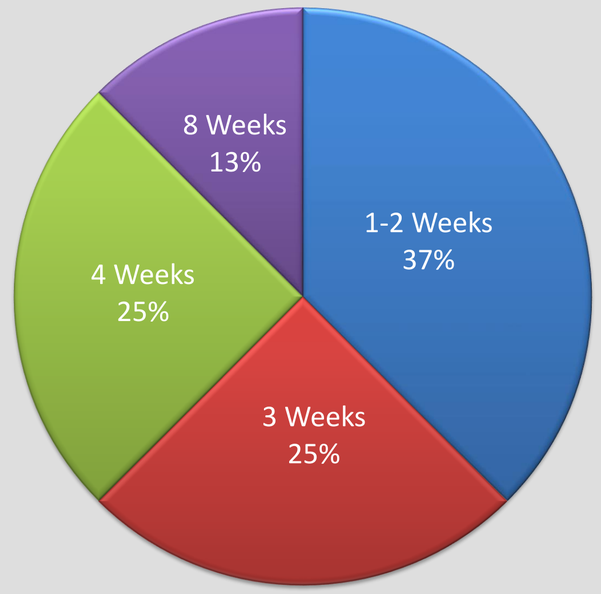
RESULTS

Institutional Demographics and Training Requirements	
Site type (n=8)	
University or Hospital based clinic affiliated with a teaching hospital	3 (37.5%)
University or Hospital based clinic not affiliated with a teaching hospital	4* (50%)
Military Clinic	1 (12.5%)
Indian Health Services Center	1* (12.5%)
Institutional Training required	
CITI Training	7 (87.5%)
Institution-specific online courses	6 (62.5%)
Biosafety/environmental health safety	1 (12.5%)

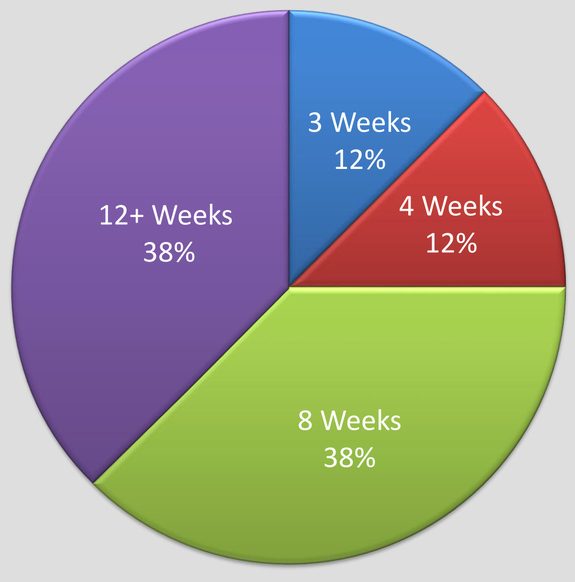
*One site submitted IRB to both a University associated with a teaching hospital and an Indian health service center

Individual IRB Requirements	
Submission Format (n=8)	
Paper only IRB	37.5%
Paper and Web-based	25%
Web based only	37.5%
Submission Requirements (n=8)	
Protocol	100%
Informed consent	100%
Copies of recruitment materials	100%
Verbal Scripts	87.5%
HIPAA authorizations	75%
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%

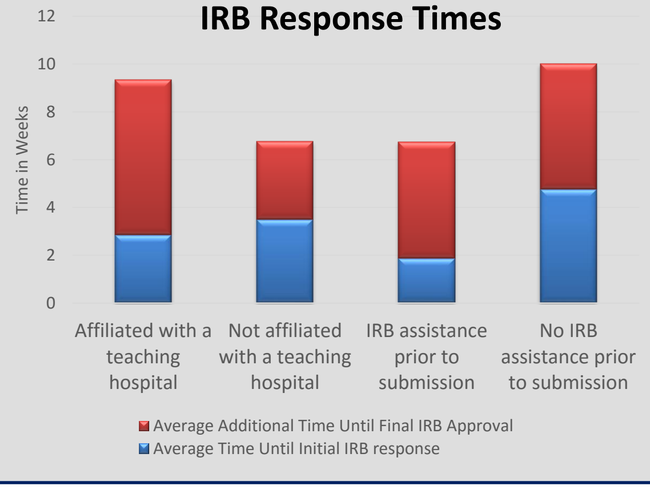
Time Until Initial IRB Response



Time Until Final IRB Approval



Influencers of Initial and Final IRB Response Times



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

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- Clinical Trial Registration: # NCT02472223 https://clinicaltrials.gov/ct2/show/NCT02472223