



# Irving Institute for Clinical and Translational Research Columbia University Medical Center/New York Presbyterian Hospital

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(Henry Ginsberg, PI)

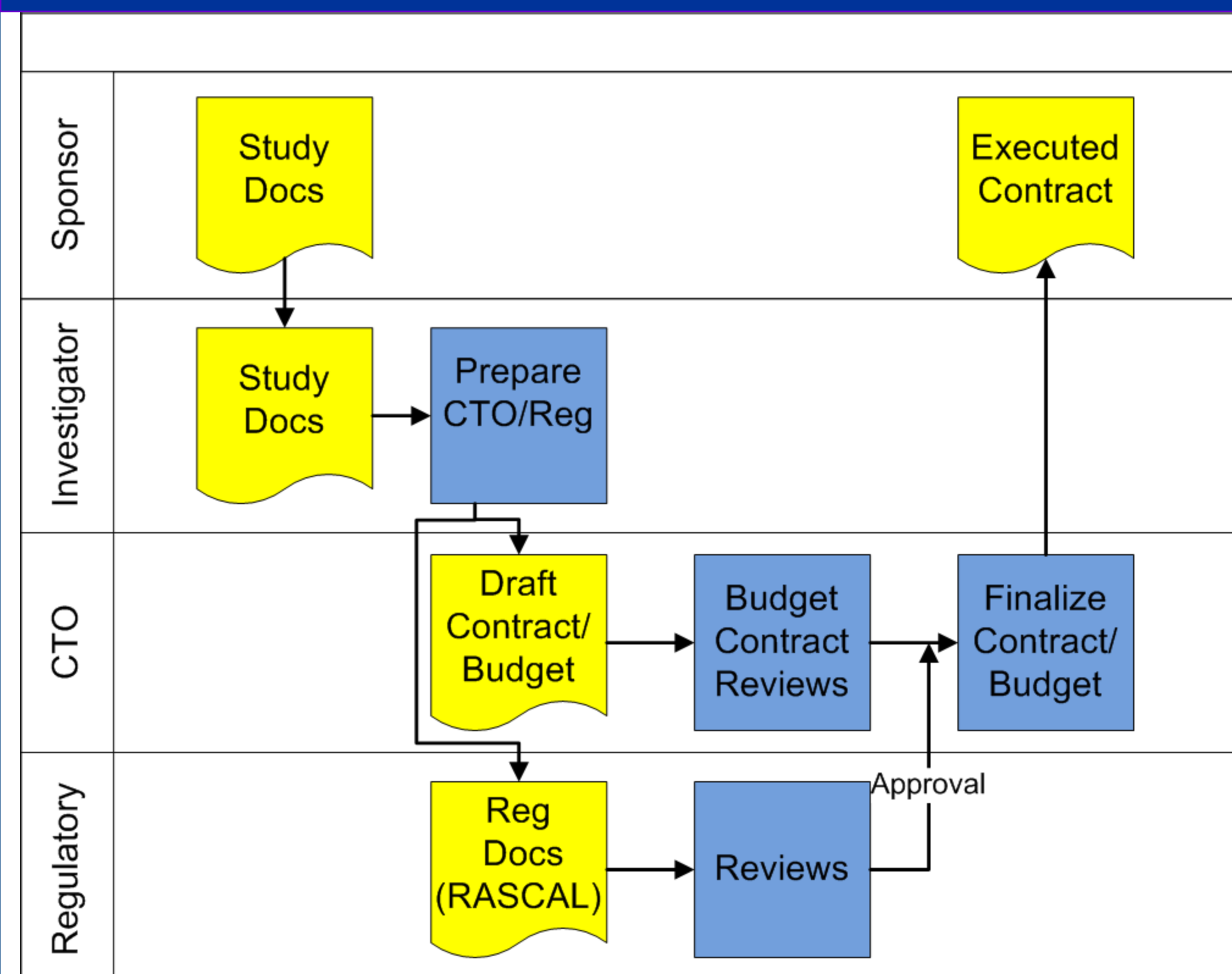
## Overview

Since 1992, the Clinical Trials Office, a joint office of the Columbia University College of Physicians and Surgeons and the New York-Presbyterian Hospital, has had the responsibility for contract and budget negotiation of all clinical trials, regardless of sponsor.

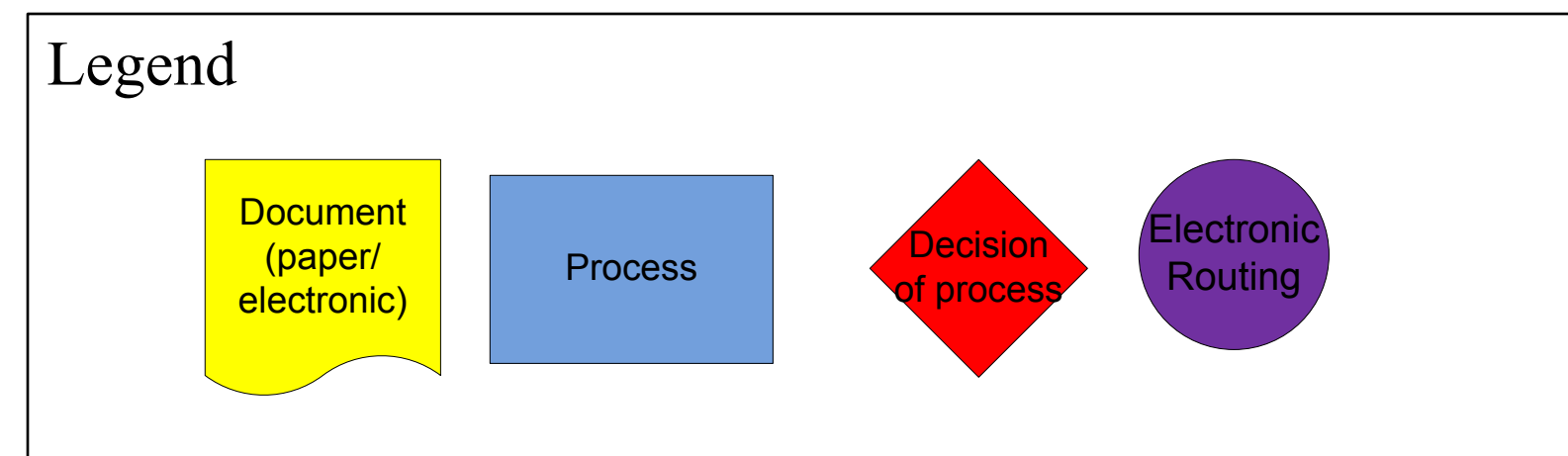
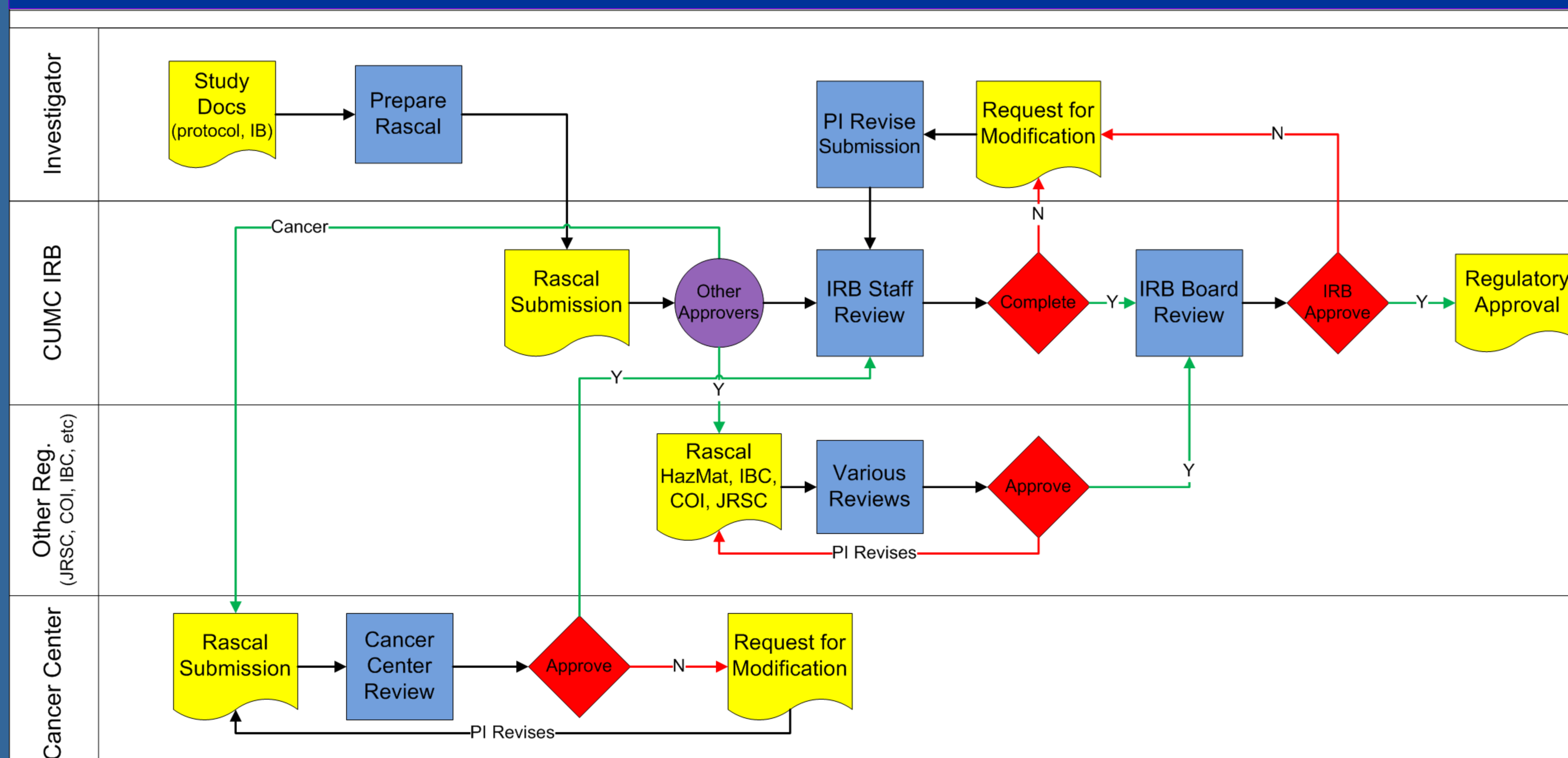
Since 1999, a single, integrated electronic system (RASCAL) for regulatory submissions has been in use. This compliance system covers:

- Human Subjects Protection (IRB)
- Cancer Center
- PCIR (in development)
- Animal Care (IACUC)
- HIPAA
- Hazardous Materials
- Radiation Safety (in development)
- Institutional Biosafety
- Conflict of Interest
- On-line training and tracking of training

## Overall Process for Externally Sponsored Clinical Trials



## Regulatory Process with Electronic System



## Metrics on Industry-Sponsored Clinical Trials

	Total	Contract Finalized* (calendar days)		Budget Finalized* (calendar days)	
		Mean	Median	Mean	Median
2006	148	57	38	79	63
2007	139	56	49	63	54

\*Contract and Budget done in parallel

## Examples of Data Available

RASCAL tracks every event with a time stamp. The protocol is Submitted by the PI. The protocol is Logged In by the IRB staff and assigned to one of three boards. The protocol is Distributed by the Chair to a primary reviewer and to the Board (granting read-only access to the protocol). The protocol is Assigned to Meeting by the Chair placing it on an agenda. In the example below, the meeting date was 3/28/07 and approval was granted at the meeting. Notification came on 4/2/07 when the minutes of the meeting were approved by the Chair. Overall time = 26 days from submission to approval.

Status	Date	Person/Outcome
Approved	04/02/2007 at 15:55	Minutes approved by Chair
Assigned to Meeting	03/15/2007 at 09:33	By IRB 2
Distributed	03/15/2007 at 07:55	By IRB 2
Logged In	03/15/2007 at 16:11	By IRB 2
Submitted	03/07/2007 at 13:09	By [redacted]

In the following example (top of next column) the protocol was Returned within days of being initially submitted. There was a major omission (the sponsor's protocol was not included). The PI re-Submitted the protocol with the required document and it was Logged in and Assigned to Meeting. The Board had substantive issues and Returned the protocol. The PI re-Submitted addressing these issues and the protocol went to a second Board meeting. At that meeting, the Board approved the study, Pending proscribed changes. These were made and re-Submitted by the investigator and approved by the Chair as meeting the required changes. In this example, the overall time was 92 days, of which 42 days were with the PI.

Status	Date	Person/Outcome
Approved	09/20/2007 at 05:47	By IRB 2
Logged In	09/20/2007 at 16:49	By IRB 2
Submitted	09/20/2007 at 10:55	By [redacted]
Pending	09/14/2007 at 14:06	By IRB 2
Assigned to Meeting	09/20/2007 at 11:23	By IRB 2
Distributed	09/20/2007 at 09:19	By IRB 2
Logged In	09/20/2007 at 08:57	By IRB 2
Submitted	09/22/2007 at 10:49	By IRB 2
Returned	09/02/2007 at 12:14	By IRB 2
Assigned to Meeting	07/19/2007 at 08:56	Assigned to IRB 2
Distributed	07/19/2007 at 07:37	By IRB 2
Logged In	07/19/2007 at 13:21	By IRB 2
Submitted	07/13/2007 at 23:21	By [redacted]
Returned	07/03/2007 at 16:28	By IRB 2
Submitted	06/29/2007 at 13:45	Assigned to IRB 2

## Lessons Learned

- Fulfillment of regulatory requirements involves more than the IRB. Having an integrated system for regulatory compliance (such as RASCAL) is a powerful tool for fulfilling these requirements. In addition, the event tracking provides data that can be used for QA.
- The rules and requirements for clinical trials are complex and requirements are increasing (e.g., need to obtain Medicare-carrier approval for device trials, requirement for registration on clinicaltrials.gov).
- An electronic compliance system is more efficient than a paper-based system, but implementation requires training and education.

•The biggest delay in regulatory approval is incomplete and/or poorly constructed submissions. The solution will require a multifaceted approach. Well designed templates that help guide researchers through the process, as well as education and training of investigators and their staff in regulatory compliance, could have a major impact.

•Contracting and budgeting with industry sponsors needs to be more efficient. Process improvement can come with the use of more standardized contracts and better coordination between budget and contract review. The budgeting process needs to be structured to facilitate the translation of a schedule of events into a set of quantifiable costs. An electronic trial management system that captures the schedule of events and is linked to the institutional charge master will eventually help automate the budgeting process.

## Contact Information

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