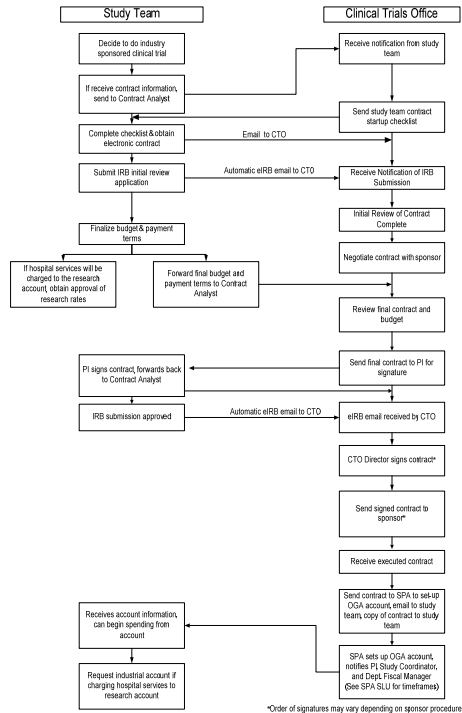


# IRB & Clinical Trial Contracting Process Improvement

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## Clinical Trial Contracting



### Process Improvements

- Reorganize to report to Director, Clinical Trials Office
  - Expertise
  - Centralization of clinical trial functions
- Integration with eIRB to facilitate negotiation
  - Staff access to eIRB
  - eIRB email notifications of submission and approval
- New tracking system ("Jellyfish")
  - Study team access to current status, metrics, reports
  - Links to eIRB study status & Oracle Grants Accounting
- Additional staff (3FTE from 1 FTE)
- Library of standard language
- Policy/procedure creation
- Streamlined account set-up process

## IRB

### Issue

'Submit to eIRB' to 'final approval date' is a time period filled with many interactions which are not all serial occurrences and don't involve "state changes" in eIRB:

- IRB review
- Cancer Scientific review
- Radiation Safety review
- OCTRI review
- Biosafety review
- IRB Analyst admin review
- Investigator responses
- Sponsor negotiations

Investigators tend to blame the IRB for any delays, so a service level understanding (SLU) was established for IRB turn-around time. The information, however, must be collected by hand because the interchanges are not captured in the eIRB.

Complete and Correct submission → IRB Review SLU = < 3weeks  
 IRB review → Review Communication Sent to PI SLU = < 5 days  
 PI Response → Final Approval SLU = < 3 days

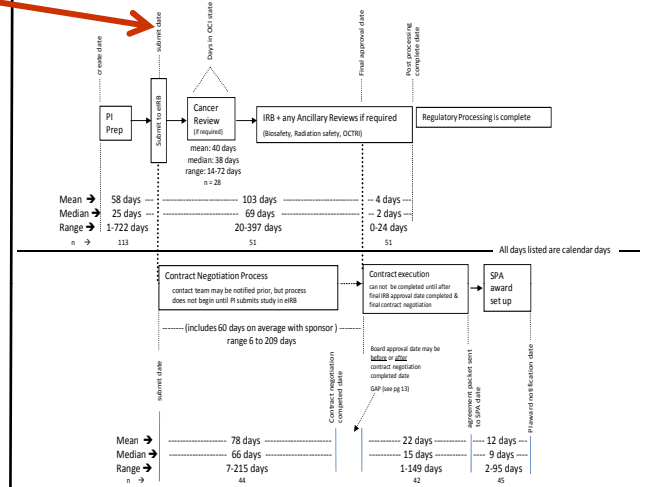
### Solution

Create eIRB flags to automate data collection. IRB analysts will set them. Review communications will have reports to educate PIs about the study's 'life'.

Pre-review	Measure time from analyst claim until work begins
Pre-review complete & correct	Date Analyst completes work with research team & judges it to be ready for review
IRB review	Date of either expedited or full board review
Communication	Date the communication goes out to PI sent
Post-review complete & correct	Date PI response to review is sufficient for approval
Post-process complete	Date all docs stamped and ready for use

## IRB/Contracting Metrics

Regulatory, Ethical & Contracting Processes—includes PI time, IRB time, & Sponsor time -- industry funded studies only



Total Time Required including regulatory & ethical and contracting (from submit date until PI award notification date) = 132 days on average  
 NOTE: because the regulatory and contracting process may run in parallel you cannot sum the averages of all the activities to get the average of the total process end to end.

### Lessons

- IRB milestones not collected well
- Scientific review committee bottlenecks
- PI assistance appeared important
- PI & Sponsor time significant
- IRB vs. Contracting last to finish: 50/50

### Future Directions

- eIRB flags
- IRB coordinated communication pilot
- Examine closer, effect of infrastructure services
- Quantify better, PI education, promote infrastructure services, IRB study timeline report
- Continuous process improvement