

# IRB Metrics Workgroup

## 2014 IRB Workflow Study

Michael Caligiuri, Karen Allen, Nate Buscher, Lisa Denney, John Fontanesi, Cynthia Gates, John Heldens, Kip Kantelo, Anthony Magit, Dan Redline, Christopher Ryan, Rachael Sak, Michael Thomas

October 16, 2015

# 2014 IRB Workflow Study

## Goals & Approach

- Examine IRB workflow metrics from UC biomedical campuses to identify best practices
- 808 clinical trials collected in REDCap over 1 year
- Trial and institutional characteristics were analyzed as for their impact on IRB review times

# Notable Results

- Pre-IRB meeting administrative review times decreased with more IRB meetings/month
  - Industry funded trials were faster
  - PI-authored trials took longer than sponsor-authored
- Variables associated with decreased IRB review times
  - Greater staffing
  - Fewer protocols/FTE

## Notable Results (cont.)

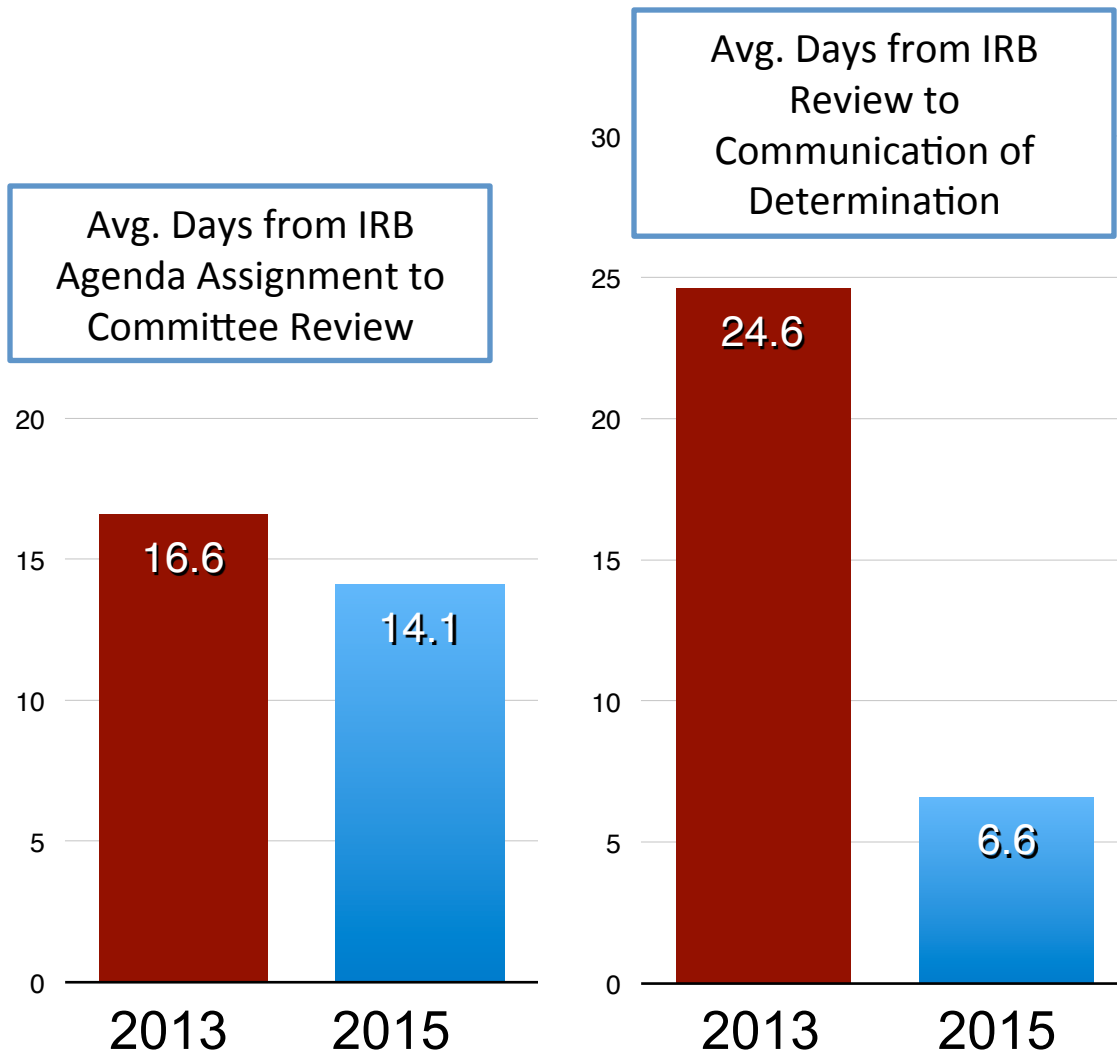
- Total review time increased significantly with greater # of ancillary reviews at 3 campuses
- Radiation safety review contributed to significant increase in total review time for some campuses

# Findings Point to Best Practices

Inter-campus variability in approval times suggests several best practices

- One campus showed shorter pre-review and IRB approval time for Phase 1 trials
- Another posted significantly shorter total review times for industry-sponsored trials
- 2 campuses demonstrated shorter radiation safety review times

# Improving Turnaround Time at UCD



## Steps Taken:

- Increased staffing by 3 FTEs
- Removed unnecessary steps; increased pre-IRB screening and rapid contact with PI to address issues earlier
- Training : 7 FTEs now CIP certified
- All expedited reviews completed by designated staff reviewers
- Committee members reach out to PIs to obtain clarification and revisions

# Moving Forward

- Full manuscript in preparation
- Follow-up study to look at interactive effects of institutional and clinical trial characteristics on IRB workflow
- Based on outcomes, campuses will be encouraged to adopt best practices identified and re-evaluate one year later