

# UC IRB Metrics

Proposed Multi-Campus Project

UC BRAID

University of California Biomedical Research  
Acceleration, Integration & Development

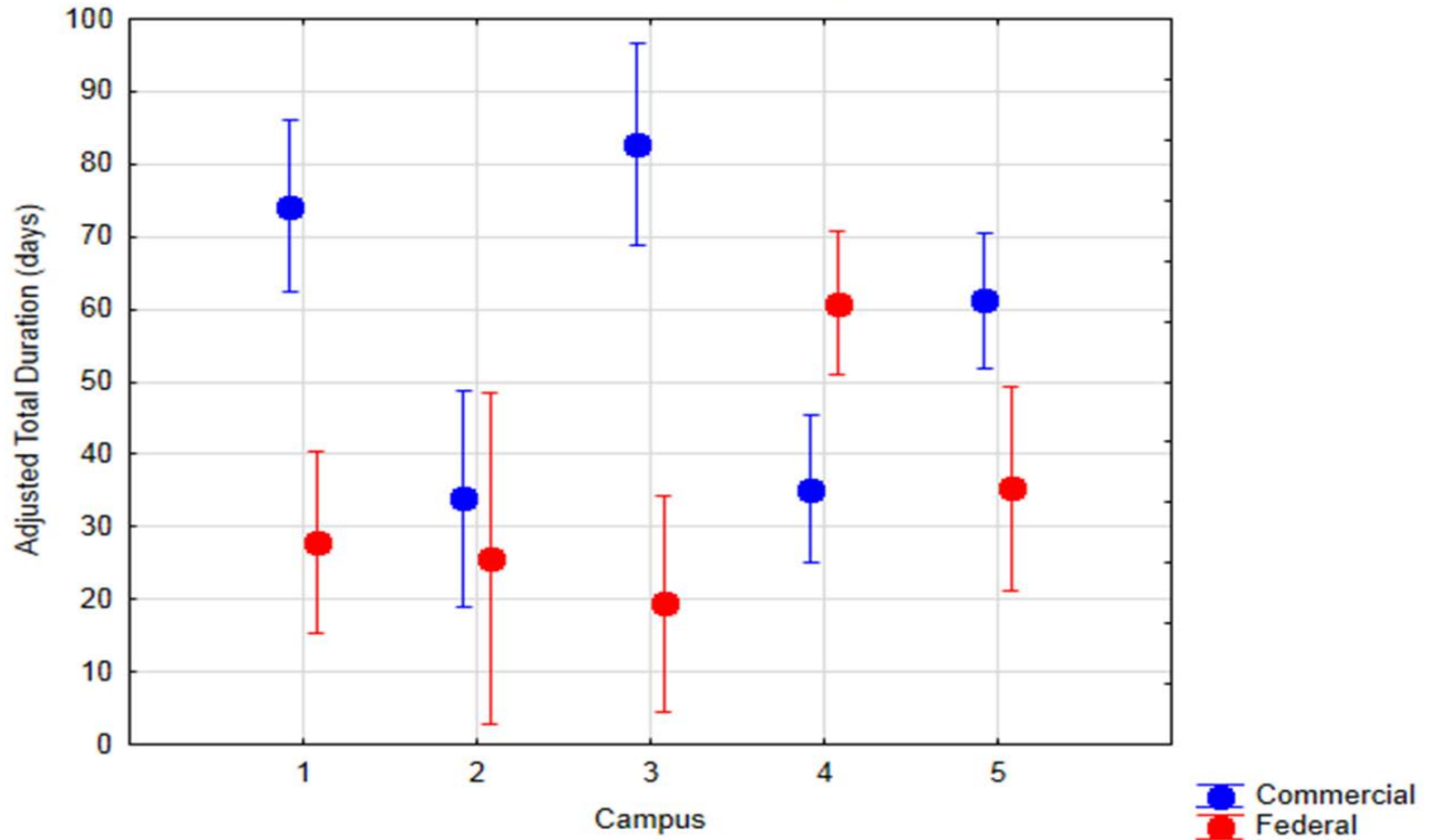
# IRB Metrics Pilot Study - 2011

Campus Code	Number of Studies	Median Pre-Meeting Duration	Median Post-Meeting Duration	Median Total Approval Time
1	22	21.00	38.00	60.50
2	10	23.50	22.00	38.50
3	15	28.00	36.00	63.00
4	32	35.00	28.00	75.50
5	29	17.00	48.00	65.00
Average		28.00	33.00	64.00

# Effort of Funding Source on Approval Time

Current effect:  $F(4, 93)=4.3762, p=.00275$

Vertical bars denote  $\pm$  standard errors



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# Limitations

- Insufficient data
- Potential selection bias
  - no Phase I trials for campus 2
  - no Oncology Phase I trials for campus 3
- Cannot evaluate moderator effects
  - Campus-specific IRB Characteristics

# Goals of Prospective IRB Metrics Project

- To develop best practices for reviewing early phase clinical trials
- To identify sources of variability in approval times
- To reduce between-campus variability

# Proposed IRB Metrics - Project II

- Project Period: 1/1/2014 - 3/31/2014
- Eligibility: All intervention (clinical trial) research studies approved by a full-board IRB
- Input Variables
  - Campus-specific Characteristics
  - Project Characteristics
  - Project Quality and Quality of IRB Review
- Utilize REDCap environment to standardize data entry

# Proposed IRB Metrics - Project II

- Campus-specific Characteristics
  - Number of biomedical IRBs
  - Number of FTEs in direct support of IRBs
  - Total volume of monitored research

# Proposed IRB Metrics - Project II

- Project Characteristics

IRB Tracking #	Committee ID
Title	Hem-Onc (Y/N)
Sponsor	Phase (I-IV)
Funding source (F/C)	Multi-site (Y/N)
PI initiated (Y/N)	# Ancillary reviews
IND (Y/N)	HDE (Y/N)
IDE (Y/N)	Other ?



# Proposed IRB Metrics - Project II

- Qualitative Analyses
  - Quality of Initial Submission
    - % items complete from submission checklist
  - Quality of IRB Review
    - ?