

Optimization of Resources Between IRBs and Cancer Centers: A UCSF Model

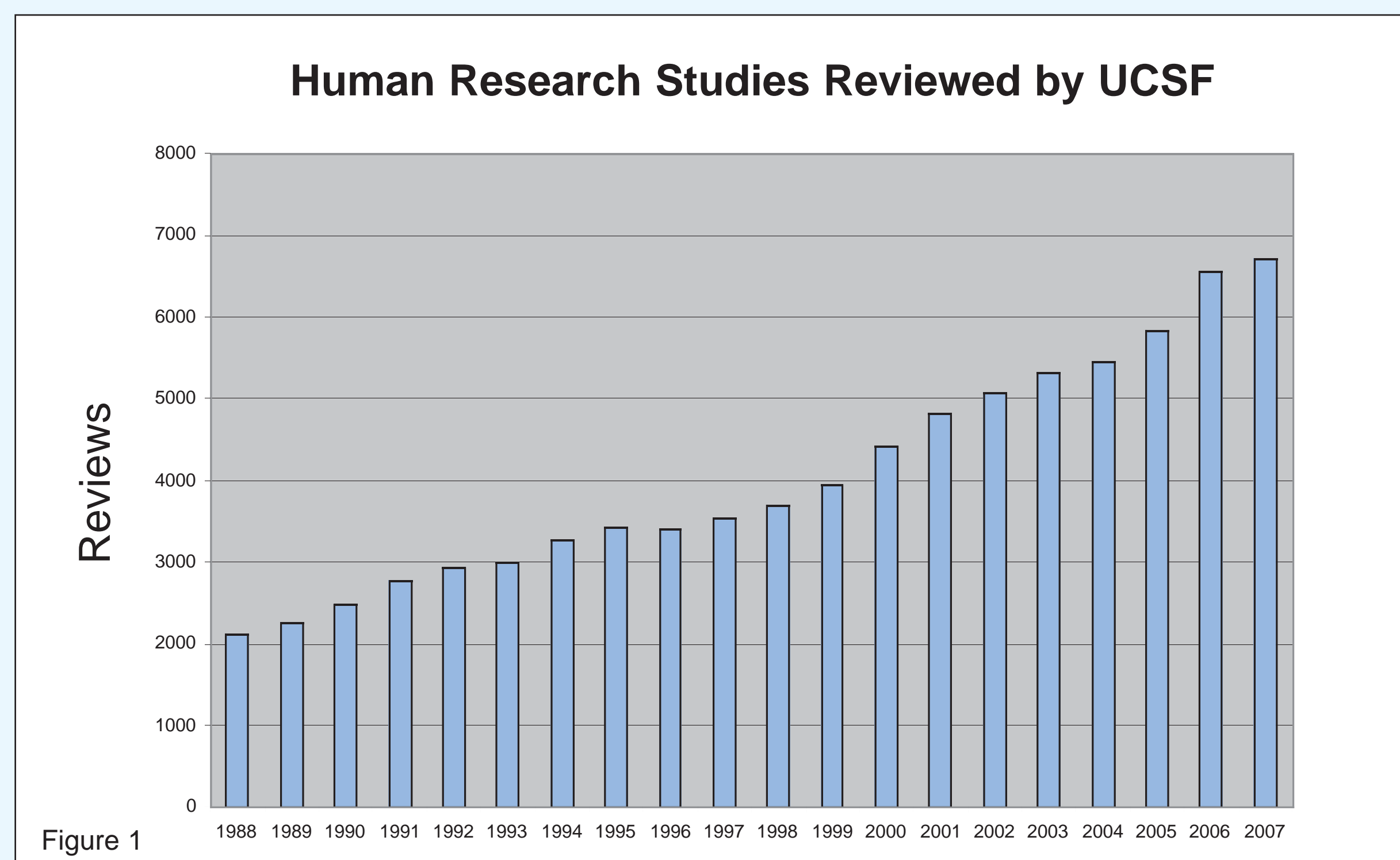
John Heldens, Marlene Berro, Joel Palefsky, Alan Venook

University of California, San Francisco USA



Background

As the number and complexity of IRB applications continues to increase, new models of review are being explored. (Figure 1)



The UCSF Human Research Protection Program (HRPP) has been actively pursuing IRB reliance agreements and memoranda of understanding (MOU) with other institutions to help manage this growing workload.

The goals are to:

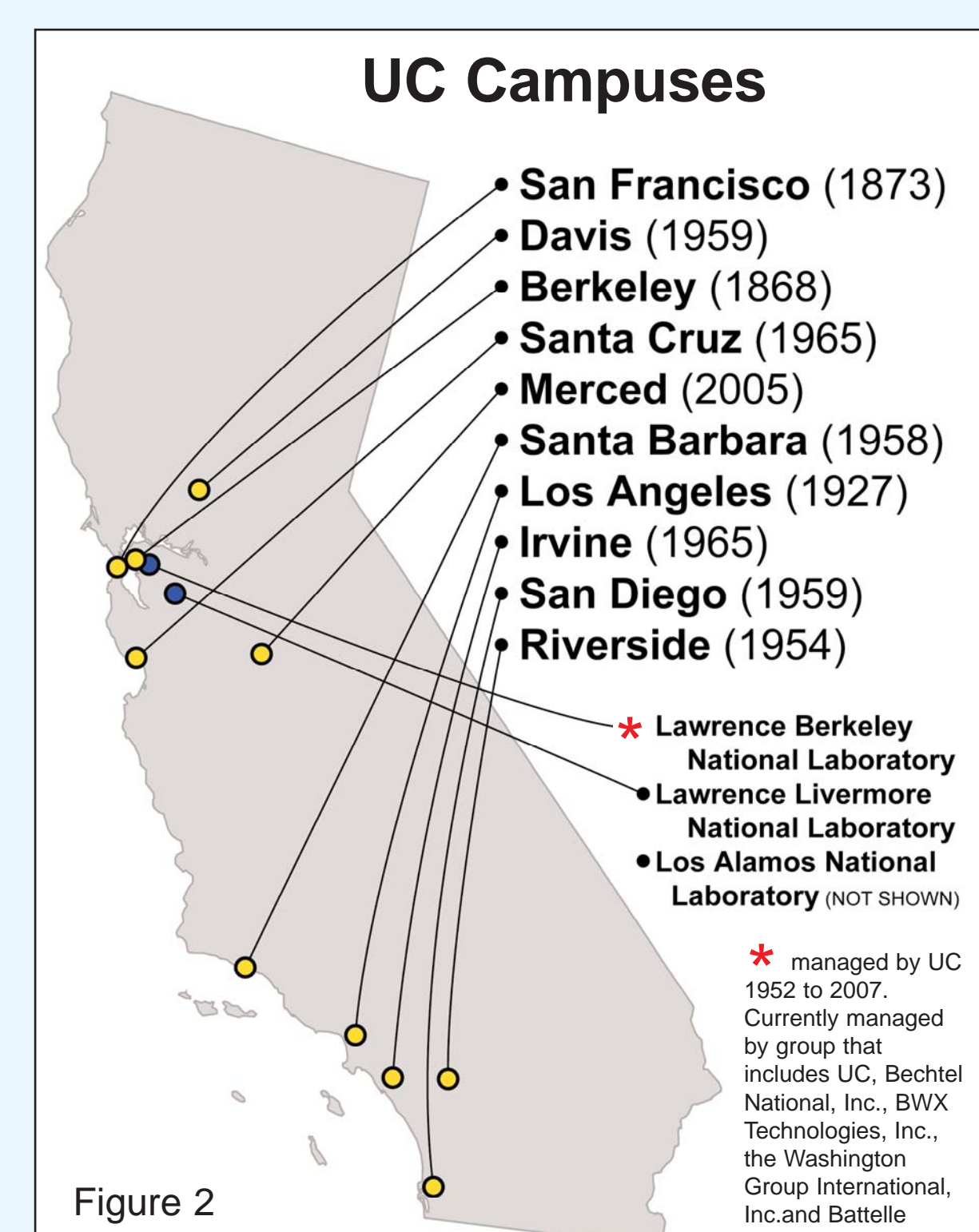
- Leverage existing resources to avoid duplicative IRB reviews
- Maintain consistent high standards for IRB reviews
- Minimize the cost, time, and effort associated with UCSF IRB review for PIs, IRB members, and HRPP staff
- Preserve protections to human subjects

These efforts to leverage IRB resources began with a collaboration between the UCSF Cancer Center and HRPP to accept the reviews of the NCI Central IRB (CIRB). The CIRB's existing systems and procedures provided a model for UCSF to apply to other IRBs.

UCSF HRPP regularly reviewed research that the CIRB also reviewed and approved. The UCSF HRPP had historically worked closely with the Cancer Center Protocol Review Committee (PRC) to make sure that oncology trials were not reviewed by an IRB until the studies had received a contingent approval from the PRC.

Using CIRB as a model, UCSF and other UC campuses worked on creating a memorandum of understanding (MOU) to allow for any UC IRB to rely on the review of another UC IRB for expedited and exempt research taking place at more than one UC campus. Separately, UCSF, UC Davis, and UC Berkeley have an MOU allowing IRB reliances for full committee studies. (Figure 2)

In addition, an MOU was signed between UCSF and Community Medical Centers (CMC) allowing an IRB reliance agreement for UCSF-funded research taking place solely at CMC facilities in Fresno.



Aim

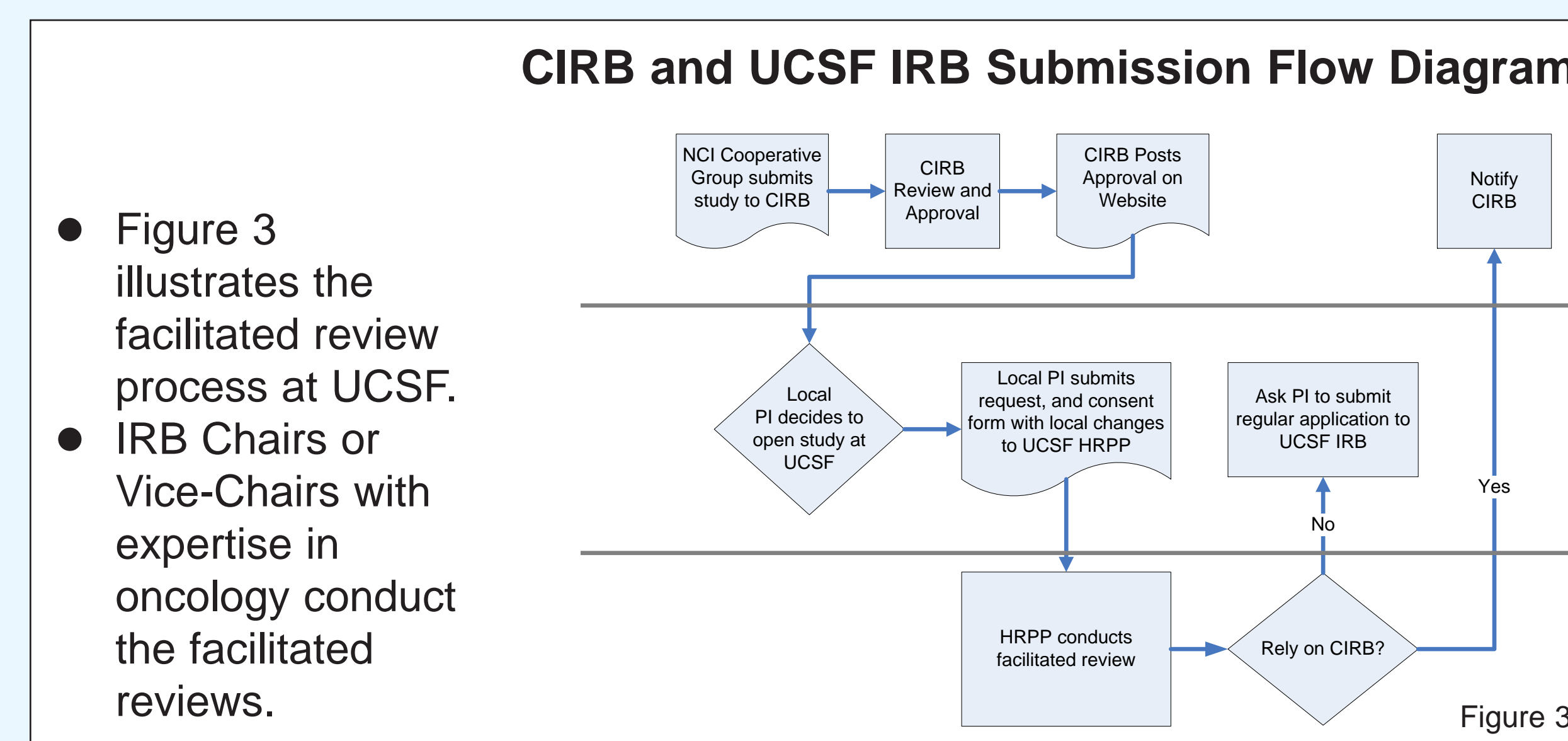
Characterize the impact on HRPP and UCSF from efforts to rely on other IRBs.

Methods

- To evaluate the value of IRB reliance agreements, we conducted a retrospective review of data from our IRB's database. We only included studies requiring full committee review, and studies that were ultimately approved. At this time the UCSF HRPP relies on a paper-based system, and current data available for evaluation is limited.

For this analysis we used:

- ~ Review Type = Full Committee
 - ~ Review Status = Approved
 - ~ IRB = CIRB, UCSF, Other UC, or CMC
 - ~ Receipt Date
 - ~ Approval Date
 - ~ Department
 - ~ Principal Investigator
- To compare time to approval, analysis was limited to research reviewed by CIRB or a UCSF IRB. Analysis was limited to Principal Investigators from the Department of Pediatrics to control for differences between, investigators, research staff, and departments.



- Figure 3 illustrates the facilitated review process at UCSF.
- IRB Chairs or Vice-Chairs with expertise in oncology conduct the facilitated reviews.

Results

Figure 4: Studies Reviewed by Non-UCSF IRBs on behalf of UCSF Human Research Protection

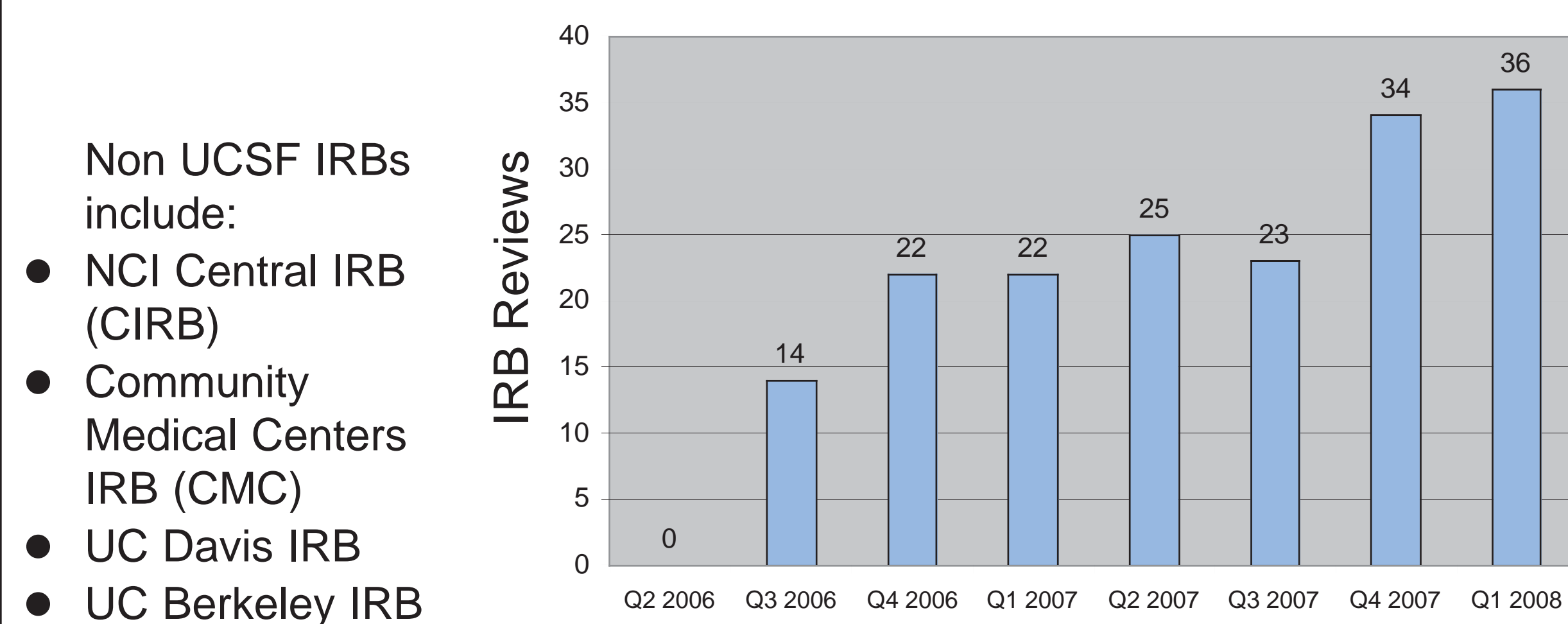
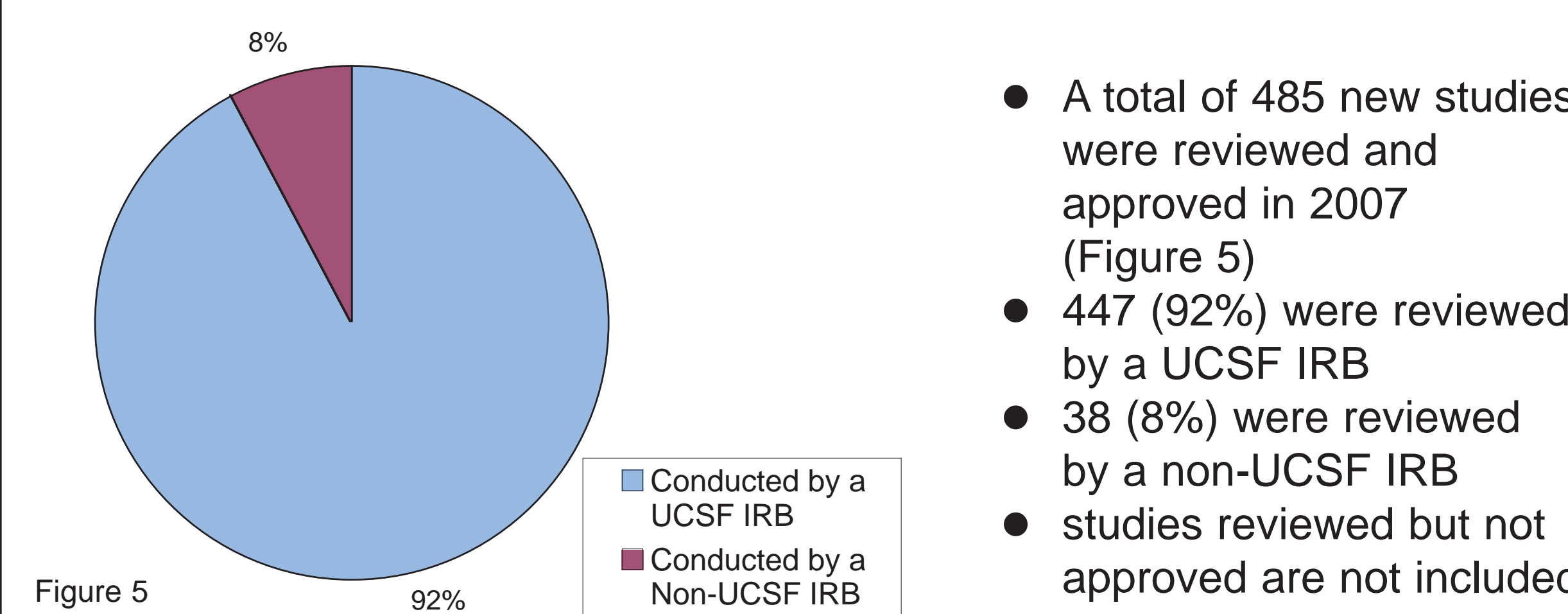


Figure 5: Full Committee Initial Reviews in 2007



- A total of 485 new studies were reviewed and approved in 2007 (Figure 5)
- 447 (92%) were reviewed by a UCSF IRB
- 38 (8%) were reviewed by a non-UCSF IRB
- studies reviewed but not approved are not included

Results (Continued)

- To date, reliance on other IRBs has saved UCSF approximately 8 IRB meetings.
- Using current UCSF IRB fee as a measure of cost, reliance on other IRBs has saved UCSF about \$155,800 to date.
- Based on member estimates of IRB preparation time, reliance on other IRBs has saved IRB faculty approximately 672 hours.

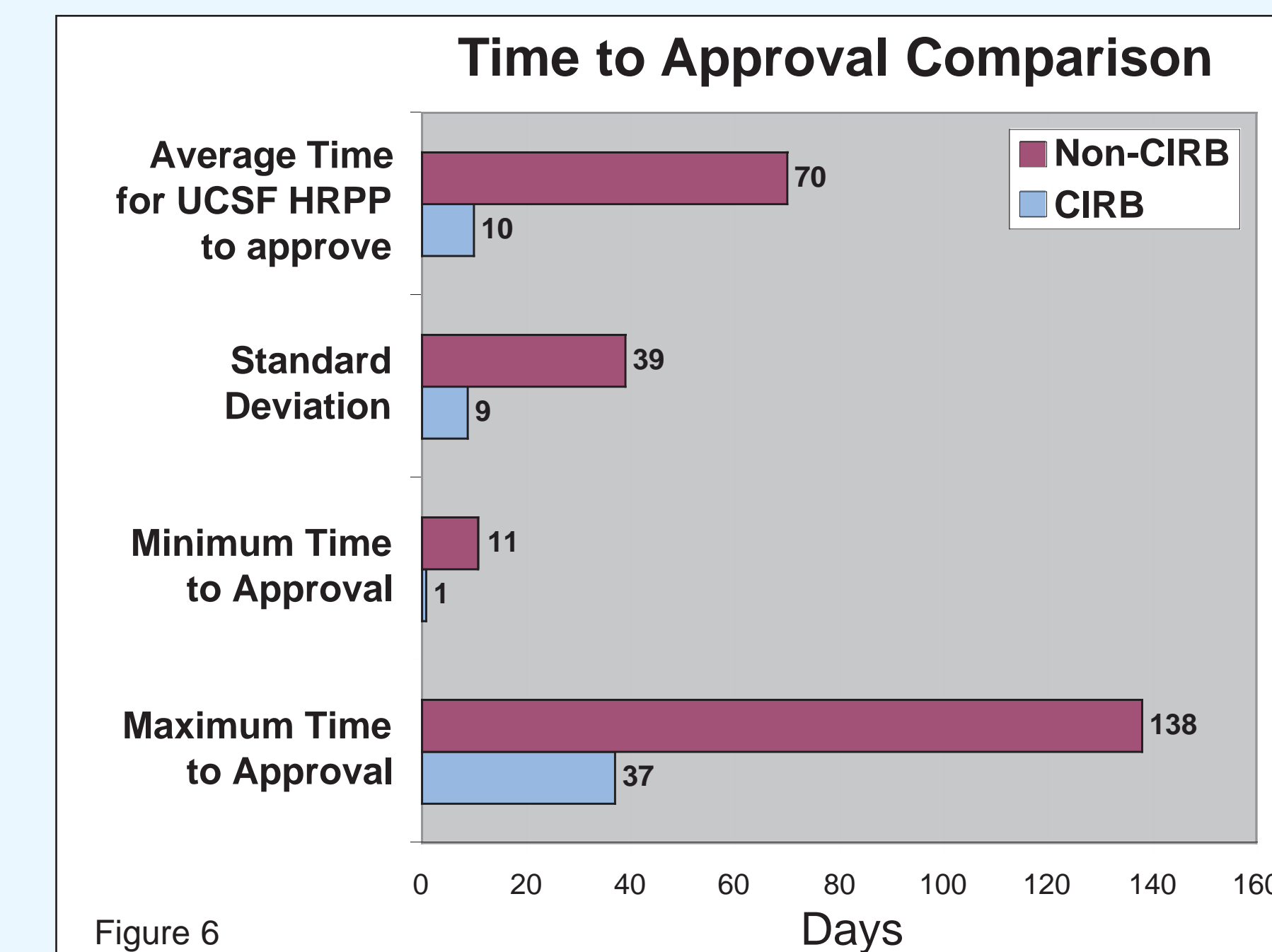
- Not included in this analysis are the efficiencies accrued to local PIs and UCSF's IRB from not having to report and review off-site AEs.

Time to Approval Comparison

- 8 investigators from the Department of Pediatrics submitted full committee applications eligible for CIRB review from 7/20/07 through 3/32/08. These same investigators also submitted full committee applications which were not reviewed by CIRB.

- 43 studies were reviewed by CIRB and underwent facilitated review by UCSF. The facilitated reviewers accepted the CIRB review in every case.

- 17 studies underwent full committee review by a UCSF IRB.



Conclusions/Future Plans

- It takes significant time and commitment by HRPP staff to establish MOUs, policies and procedures for relying on other IRBs. However, these start up costs are small compared to time and effort saved by PIs, IRB members, and HRPP staff, without any dilution of protections for human subjects.

Future Plans:

- The UCSF Cancer Center has recently agreed to provide funding for one FTE in HRPP. This position will be hired and supervised by HRPP, and will concentrate on cancer center research.
- Similar arrangements have been reached with the SFVAMC so that VA staff will perform administrative tasks formerly performed by HRPP staff.
- UCSF is in the final stages of selecting a system to allow for paperless IRB review. A study to evaluate the impact of the system is being planned and will include additional metrics.

Acknowledgements

Special thanks to Sharon K. Friend, MS, CIP, for her leadership. Thanks also to Lisa Voss, Susie Corl, Richard Wagner, and the entire HRPP staff. This publication was made possible by Grant Number UL1 RR024131-02 from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH), and NIH Roadmap for Medical Research.