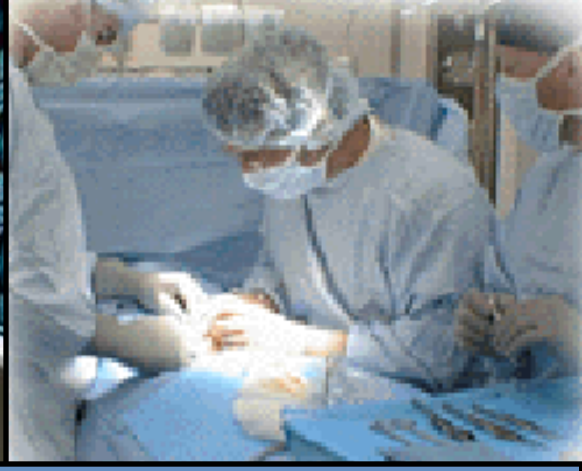
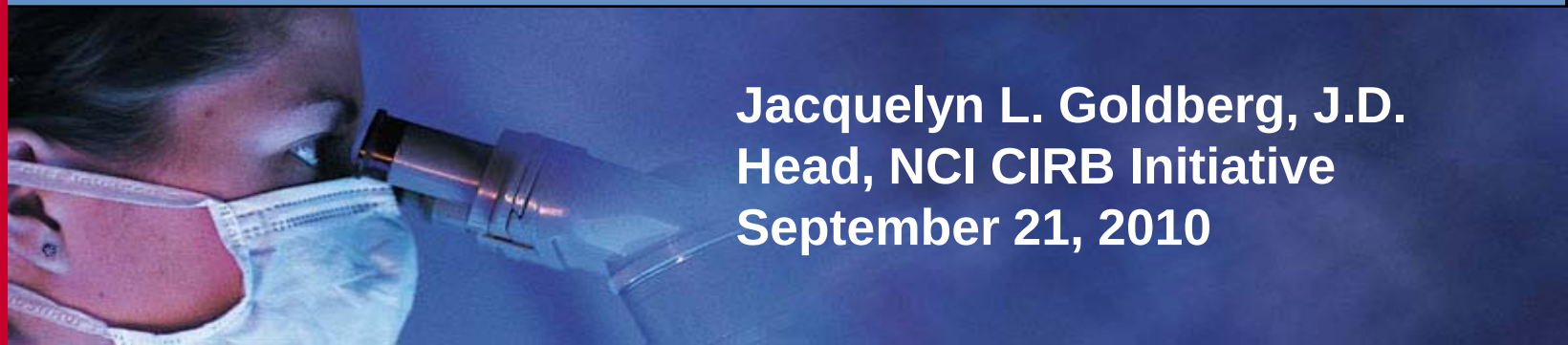
National Cancer Institute



NCI Central IRB Initiative Update



Jacquelyn L. Goldberg, J.D.
Head, NCI CIRB Initiative
September 21, 2010

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Topics

- Background
- Metrics
  - Enrollment and Utilization Data
  - Process Improvement
- Accreditation

Background

- Central IRB Initiative
  - Adult CIRB (started 2001)
    - Reviews adult Phase 3 Cooperative Group trials
  - Pediatric CIRB (started 2004)
    - COG phase 2, 3 and pilot studies
- Facilitated Review Model
  - Review model is a partnership with the local IRB
    - If local investigator wants to open a trial s/he downloads the protocol, consent and already completed application from the CIRB website and submits it to local IRB
    - Local IRB downloads CIRB review documents (primary reviews, correspondence, meeting minutes)
    - Local IRB chair or subcommittee reviews documents for local context concerns; full Board does not meet

Background

- If local IRB Chair/subcommittee has no concerns the CIRB becomes the reviewing IRB for that protocol at their institution
- The CIRB reviews all subsequent amendments, annual continuing reviews and unanticipated problems distributed by the Coordinating Group
- If IRB Chair/subcommittee has local context concerns they can review the protocol at their local IRB and not use the CIRB; i.e. use of the CIRB is determined on a protocol-by-protocol basis

CIRB Profile

Total Number of Institutions Enrolled	295
Number of Institutions using Adult CIRB only	165
Number of Institutions using Pediatric CIRB only	44
Number of Institutions using both Adult and Pediatric CIRB	86
Total Number of Institutions Enrolled including other institutions relying on their IRB	880
Total Number of NCI Designated Cancer Centers enrolled out of 59 eligible (36 have conducted at least one FR; 5 apparently using CIRB documents)	41

Current as of 08/31/2010

CIRB Profile

- Number of Facilitated Reviews Conducted 11,376
  - Adult 6,725
  - Pediatric 4,651

- Number of Total Studies Available for Facilitated Review 248
  - Adult 159
  - Pediatric 89

Current as of 08/31/2010

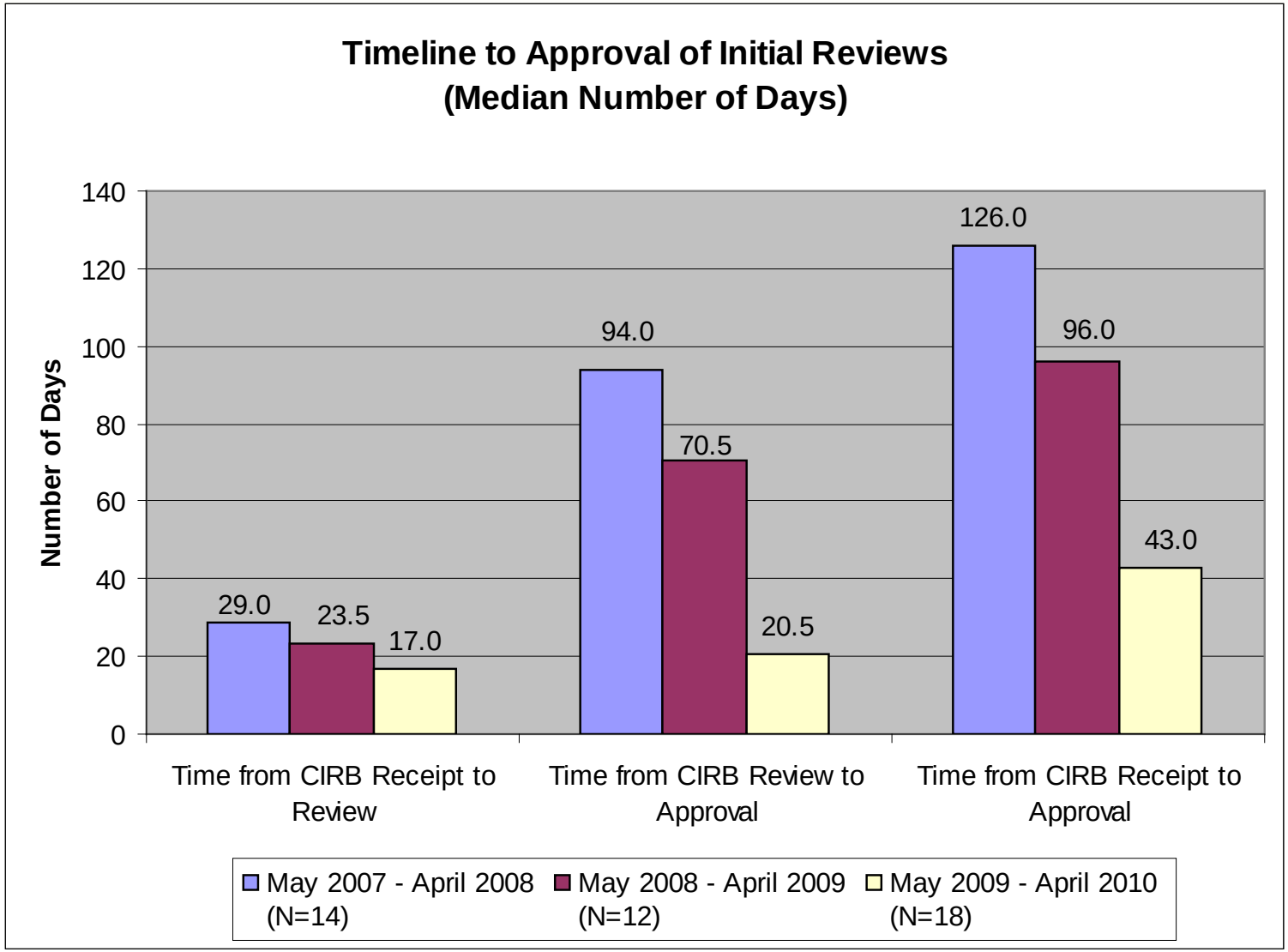
Process Improvement

- Parallel Review
  - CIRB and Cooperative Group receive CTEP approved protocol at the same time; this allows sites not using the CIRB to begin their own local IRB process parallel with the CIRB
- Timelines
  - Set mutually agreed upon timelines with Groups for responses to CIRB stipulations
  - Eliminated requirement for Groups to amend their Informed Consent Document (ICD) per CIRB stipulations
- Improved communication
  - Group PIs, statisticians, CIB staff attend CIRB meeting and PRN teleconferences

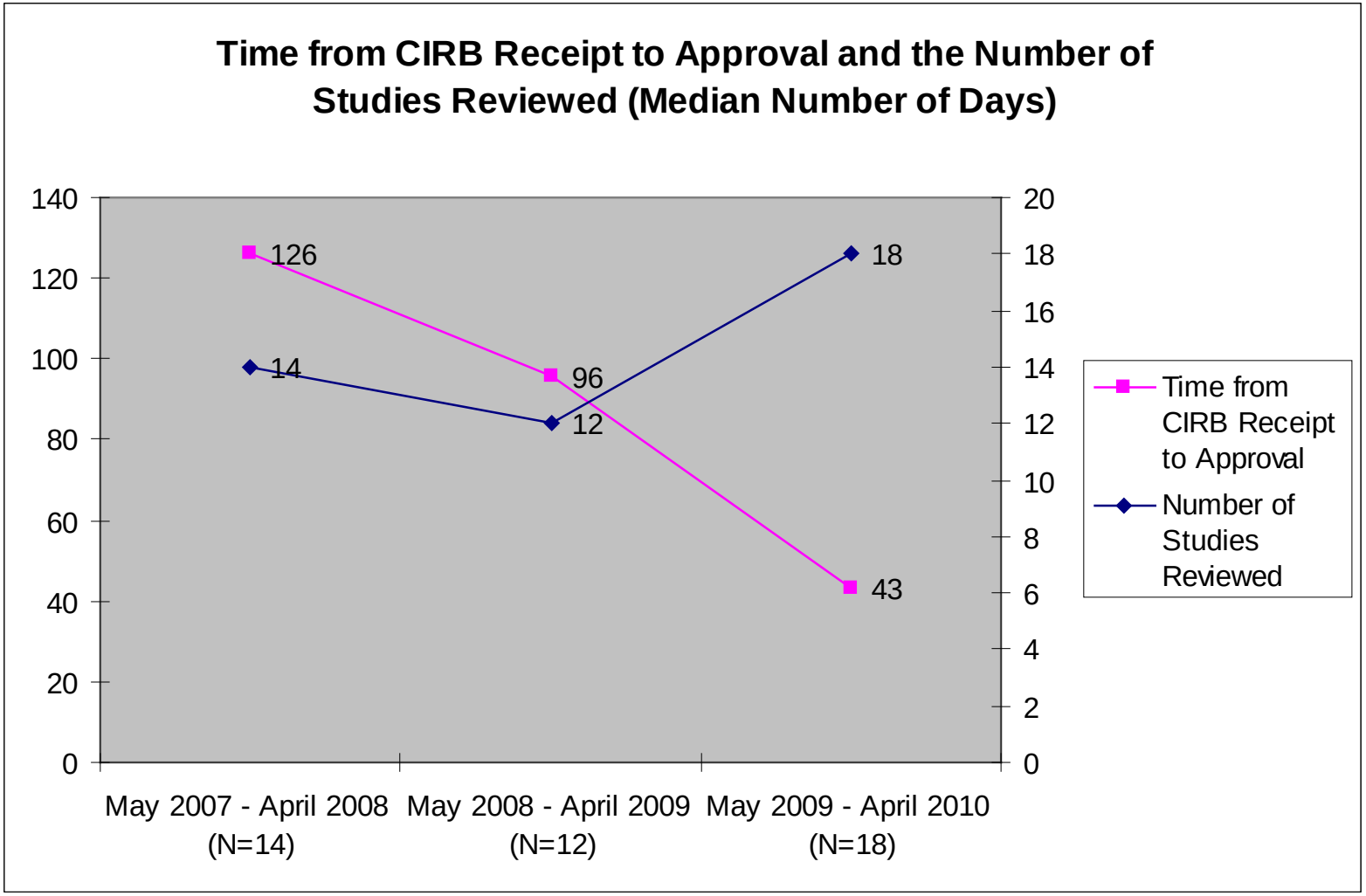
Metrics: CIRB Stipulations Requiring Group Response

Year	Number of Protocol Stipulations (Median)	Number of ICD Changes (Median)	Number of Group Resubmissions (Median)
May 2007 – April 2008	7	9	2
May 2008 – April 2009	4	14	1
May 2009 – April 2010	0	6	1

Metrics: Initial Review Timeline Comparison



Metrics: Comparison of Time to Approval and Number of Studies Reviewed



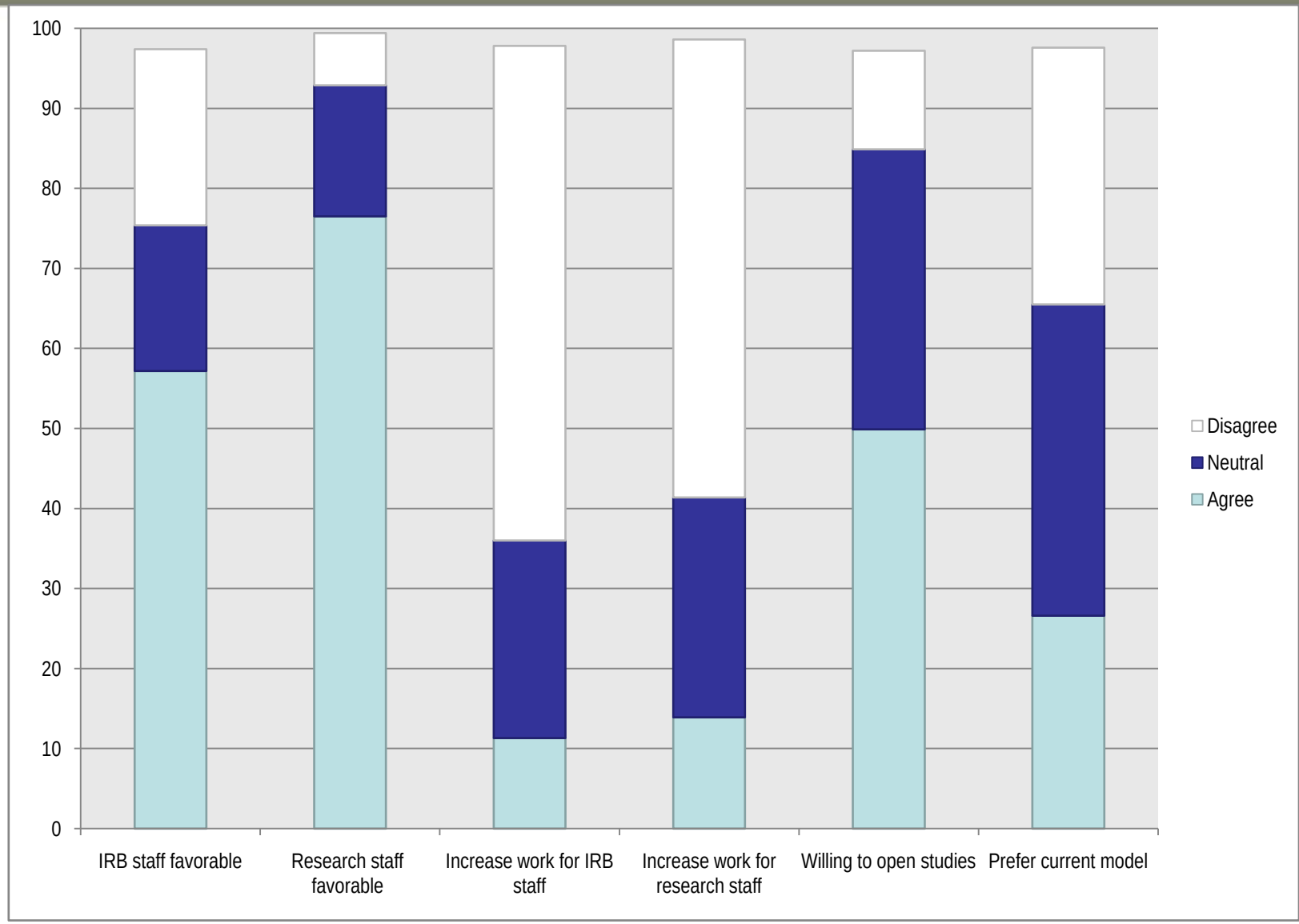
Accreditation

- **Pursuing accreditation**
  - **Association for the Accreditation of Human Research Protection Programs (AAHRPP) accredits IRBs**
  - **Accreditation is perceived as significant marker of quality in IRB community**
  - **Accreditation would enhance recruitment efforts**
- **AAHRPP suggested redesign to "independent" model**
  - **CIRB would be the IRB of record; no need to partner with local IRB**
  - **Facilitated review would be eliminated**
  - **Encouraged us to make change because**
    - **CTEP comprehensive human subject's protection program allows the CIRB to serve as an "independent" IRB**

Accreditation

- Considerations for a New Model
  - Local context review would to take place via forms submitted to CIRB by investigators and institutions; this is an added burden and expense
  - Likely to aid recruitment of sites previously reluctant to join due to perceptions around accountability/regulatory liability
  - Want to keep currently participating sites invested

ASCO Survey Results Summary



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Pilot and Timeline

- Planning for Pilot Underway
  - Developing plans to pilot the redesign in 2011
    - Testing strategies to accomplish local context reviews
    - Testing supporting documents (SOPs, forms, educational materials)
- Timeline
  - Develop plans for pilot – 2010/2011
  - Pilot with about 20 institutions - 2011/12
  - Assess institution satisfaction, operational efficiency and feasibility - Fall 2012
  - Final decision - Late 2012