



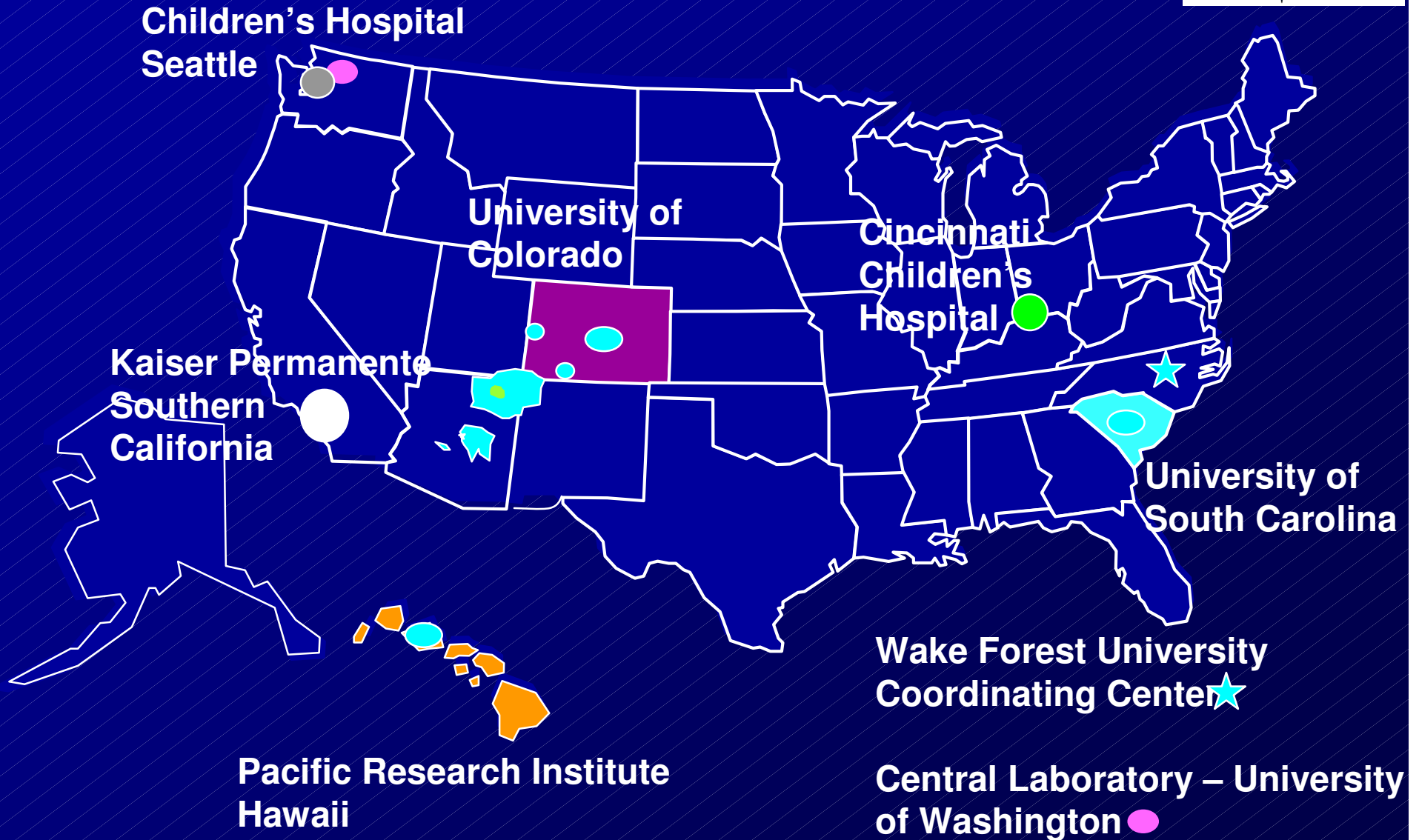
The SEARCH for Diabetes in Youth Study: Experiences with HIPAA

Elizabeth J. Mayer-Davis, PhD
Dana Dabelea, MD PhD
Richard Hamman, MD DrPH
Jean Lawrence, ScD
Larry Dolan, MD
Diana Petitti, MD MPH
Cate Pihoker, MD
For the SEARCH investigators

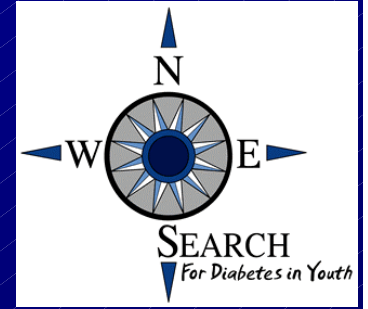
Presentation for:
Institute of Medicine
Committee on Health Research and the Privacy of Health Information:
The HIPAA Privacy Rule
June 14, 2007

SEARCH is funded by CDC/DDT and supported by NIH/NIDDK

SEARCH Study Centers



Primary Aims of SEARCH



- To estimate prevalence (2001) and incidence (2002-2009) of diabetes in youth
- Develop efficient and practical approaches to classification of diabetes types
- Compare and contrast clinical presentation and course of diabetes types
- Assess the impact of diabetes care on quality of life (short-term and long-term)

Study Design



PART 1

PART 2

**Case
Ascertainment**

HIPAA



HIPAA



Registration

HIPAA



**Prevalence and Incidence
Estimation**

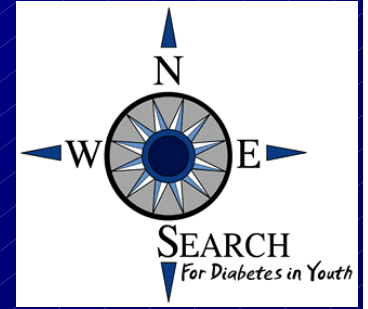
In Person Visit

- Physical exam
- Blood draw
- Blood storage
- Questionnaires
- Consent for Medical Records for incident cases

**In Person Visit
Declined**

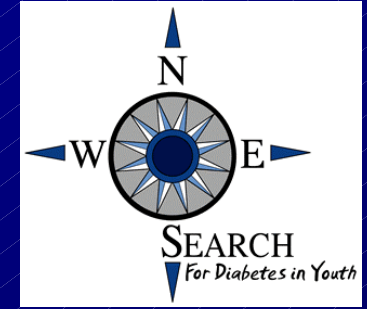
- Core information
- Medical Records

Issues with HIPAA



- Inconsistency
 - Variability across institutions at any point in time
 - Changing personnel and changing local interpretations over time
- Delay
- Cost

Inconsistency: Covered Entities



- Children's Hospitals covered entity
- Health Plan covered entity
- University Departments some covered, some not covered
- Private Research Institute not considered covered entity

- **IMPLICATION:**

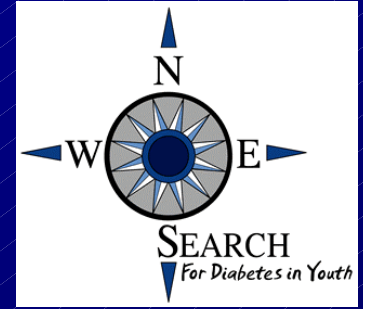
All sites worked with HIPAA covered entities, so being “not a covered entity” made no difference other than to add to confusion of investigators, universities, hospitals and other providers.

Inconsistency: Interpretation by IRB and Privacy Boards



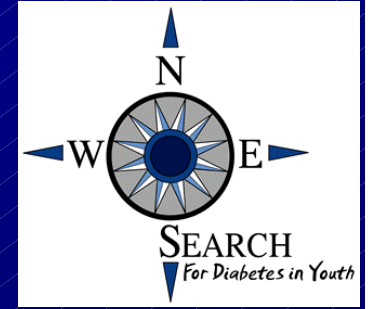
- All but 1 site dealt with multiple IRB/Privacy Boards, up to 15 per site
- Some IRBs required separate and different forms for traditional consent and release/use of PHI. Creating forms meeting institutional requirements that were still understandable for relatively low-literacy populations was challenging.
- One IRB (from one site) made contact with another IRB (from another site) because of differences in interpretation in HIPAA.
- **IMPLICATION:** Lacking standardized guidance, differences in interpretation creates conflict and delay in conduct of research

Inconsistency: “Engaged in Research”



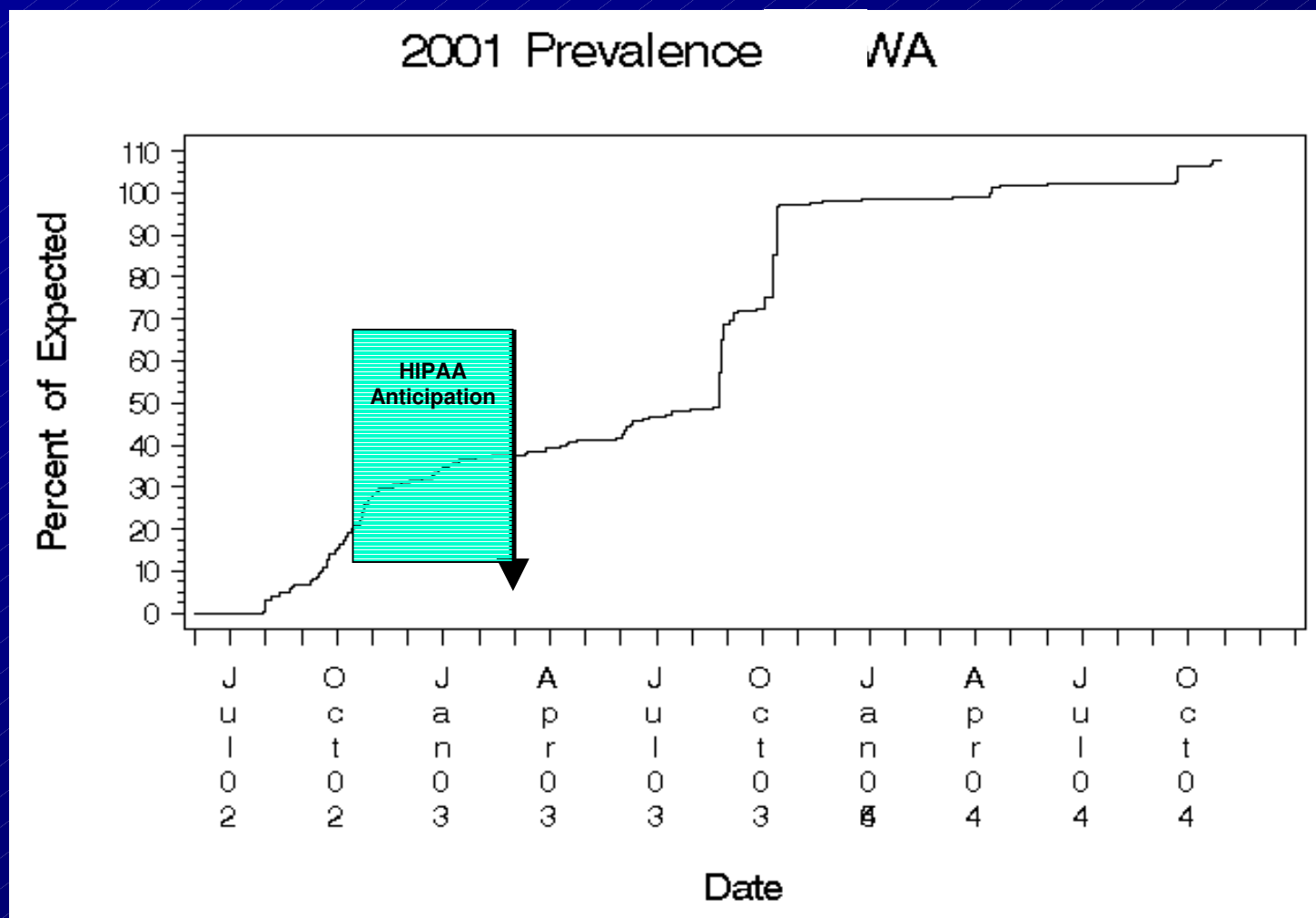
- Most IRBs: The provider may inform his/her patients about the study; this is the primary means of initiating recruitment, usually NOT considered “engaged”
- One IRB: Agreed initially, then re-considered...
The provider was required to add a new procedure for patients to sign a document indicating their willingness to have their provider inform them about any research study.
- **IMPLICATION:** Lost opportunities to inform patients about studies; response bias

Inconsistency: Waiver of Written Consent for Medical Record Review



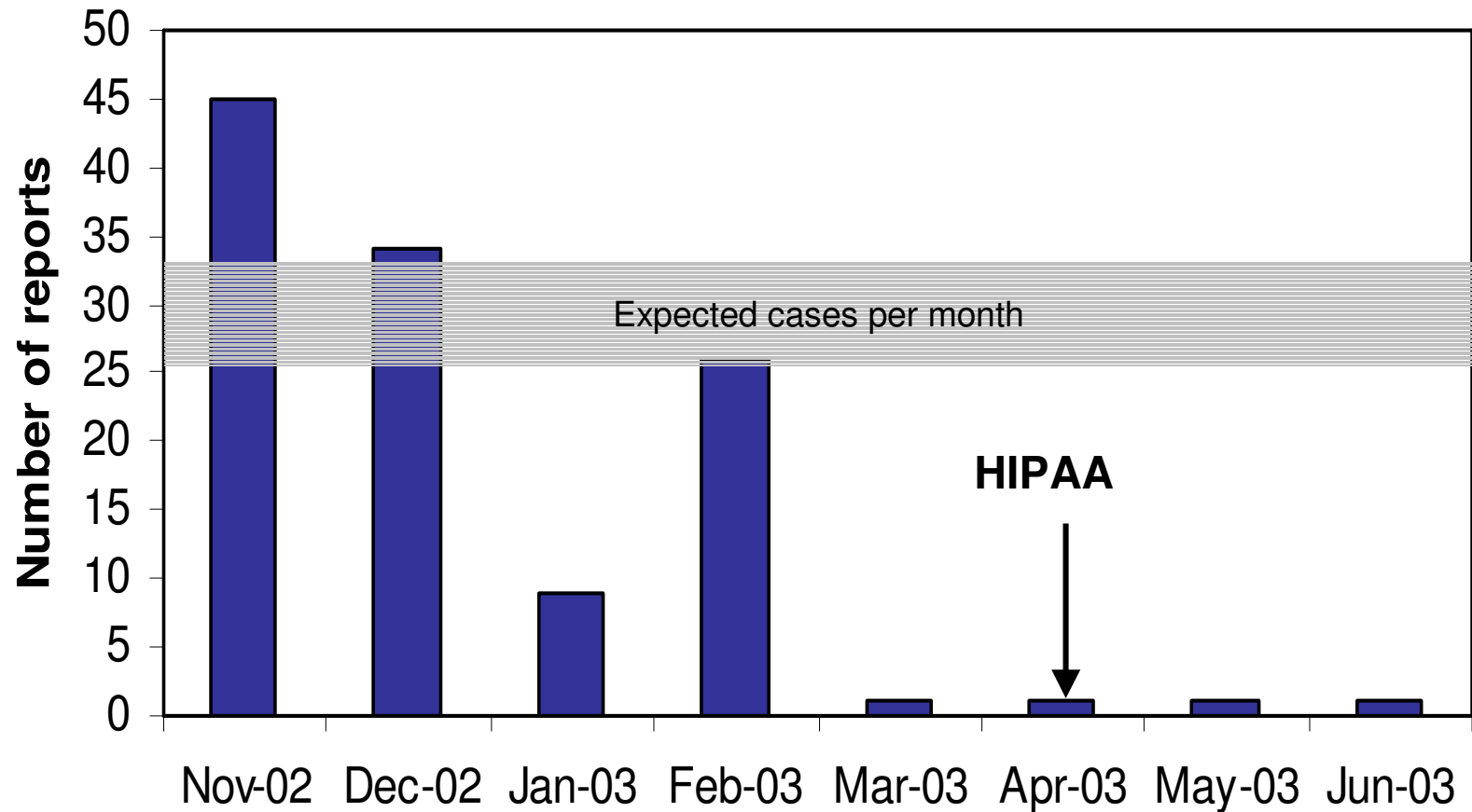
- **Waiver Status:**
 - Waiver granted – full review (full SEARCH protocol)
 - Waiver granted – partial review (limited to “Core” information)
 - Waiver not granted
- **A Glitch!**
 - Partial waiver at 1 hospital was initially granted in 2003, then withdrawn in 2005 and then reinstated.
- **IMPLICATION:** Limited generalizability of medical record data on health service utilization in sites where written informed consent was required for full review

Delay: Case Accrual at One Site





Delay: Cases reported to SEARCH Colorado SEARCH Site 2002-2003

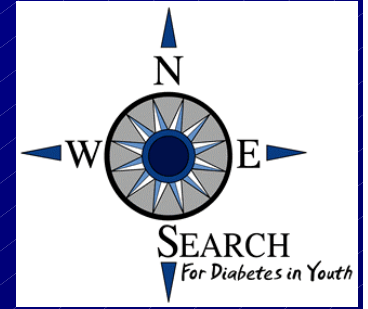


Cost of Implementing HIPAA



- 0 to 3 FTE's added across 6 centers
- Total cost difficult to estimate; some costs arose because of need to hire clinic staff to collect data
- Not less than \$500,000 and maybe as much as \$1 million (personnel, fringe, indirect)

Suggestions, Slide 1 of 2



- OHRP should provide IRBs/Privacy Boards and researchers with written guidance on the HIPAA-related issues that have been interpreted differently between institutions, within institutions and over time (e.g.)

Definition of “engagement in research”

Appropriate use of HIPAA waivers

Definition of public health surveillance

- IRBs/Privacy Boards should assure that new staff and members are adequately trained about HIPAA and that IRB/Privacy Board requirements do not change irrationally during the period of conduct of a study

Suggestions, Slide 2 of 2



- OHRP should clarify the procedures that allow researchers conducting population-based studies, including those that create disease registries, to obtain and use PHI without written consent

Direct access to contact information for recruitment should be permitted by IRBs/Privacy Boards when the research has societal benefits and the risks of contact for the individual are minimal

OHRP should describe a “safe harbor” for providers to participate in research that involves release of information that permits contact of an individual to request cooperation in research