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**2005 Annual Investigator Meeting**  
**October 10-11, 2005**  
**St. Jude Children's Research Hospital**  
**Memphis, TN**

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## CCSS Investigator Meeting

Departures to airport (Tuesday):

Sign-up for bus at registration desk

Sign-up for cabs registration desk

Be sure and check-out of hotel and bring luggage

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## CCSS Investigator Dinner

Who: Everyone attending the CCSS meeting.  
Accompanying persons are welcome.

When: Tonight beginning at 6:30pm  
(note time change)

Where: Roof-top of Peabody Hotel  
("S" on the elevator)

What: Memphis-style barbeque, Drinks, Blues

## Schedule for Working Group Meetings

12:10 – 2:15

Chronic Disease	Sklar	Room B/C
Genetics	Strong	Room D
Neuropsychologic/Neurologic	Zeltzer, Packer	Room E
Chemotherapy/RT/Surgery	Neglia	Auditorium

2:45 – 5:00

Second Malignancy	Meadows	Room B/C
Prevention and Control	Hudson	Room D
Reproductive Outcomes	Green	Room E

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# Chemotherapy, Radiation, Surgery Working Group

**Chair:** Joe Neglia

**Charge:** To establish the protocol for collection of treatment-related information for the expanded cohort (to include content, data submission, data processing/editing, quality control).

**Issues:**

Method(s) of data submission

Format

Continued collection of treatment protocol

Additions and/or deletion of specific chemotherapeutic agents

Changes in RT data collection

Changes in surgery data collection

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# Charge to Working Groups

## **ACTIVITY UPDATE**

- Inventory and Status of Current Concept Proposals  
Identify priorities and problems
- Summary of Future Concept Proposals  
Identify those to be submitted to PC in next 6 mos.
- Status of Ancillary Study Proposals
- Priorities for Future Surveys (initial cohort)

## **EXPANDED COHORT**

- Identification of items from Baseline Survey that are essential to maintain as part of data collection for the expanded cohort.
- Identification of any additional treatment-related data that should be captured.

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## New Institutional Principal Investigators

- University of California San Francisco  
Robert Goldsby replaces Art Ablin
- UT Southwestern - Dallas  
Gail Tomlinson replaces Kevin Oeffinger
- University of Alabama - Birmingham  
Jane Sande replaces Roger Berkow
- Children's Hospital of Philadelphia  
Jill Ginsberg replaces Anna Meadows
- Children's Healthcare – Minneapolis/St. Paul  
Joanna Perkins replaces Maura O'Leary

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## External Advisors

**Al Knudson, M.D., Ph.D.**

Fox Chase Cancer Center

**Sharon B. Murphy, M.D.**

Children's Cancer Research Center  
San Antonio

**Steven L. Hancock, M.D.**

Stanford University

**Susan Weiner, Ph.D.**

The Children's Cause

**Cindy Schwartz, M.D.**

Brown University

**Mark Krailo, Ph.D.**

University of Southern California

**Louis S. Constine, M.D.**

University of Rochester

**John D. Potter, M.D., Ph.D.**

Fred Hutchinson Cancer Research Center



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## External Advisors

### **GENETICS**

**Al Knudson, M.D., Ph.D.**  
Fox Chase Cancer Center

### **PREVENTION & CONTROL**

**Sharon B. Murphy, M.D.**  
Children's Cancer Research Center  
San Antonio

### **CHRONIC DISEASE**

**Steven L. Hancock, M.D.**  
Stanford University

### **NEUROPSYCH/NEUROLOGIC**

**Susan Weiner, Ph.D.**  
The Children's Cause

### **CHEMO/RT/SURGERY**

**Cindy Schwartz, M.D.**  
Brown University

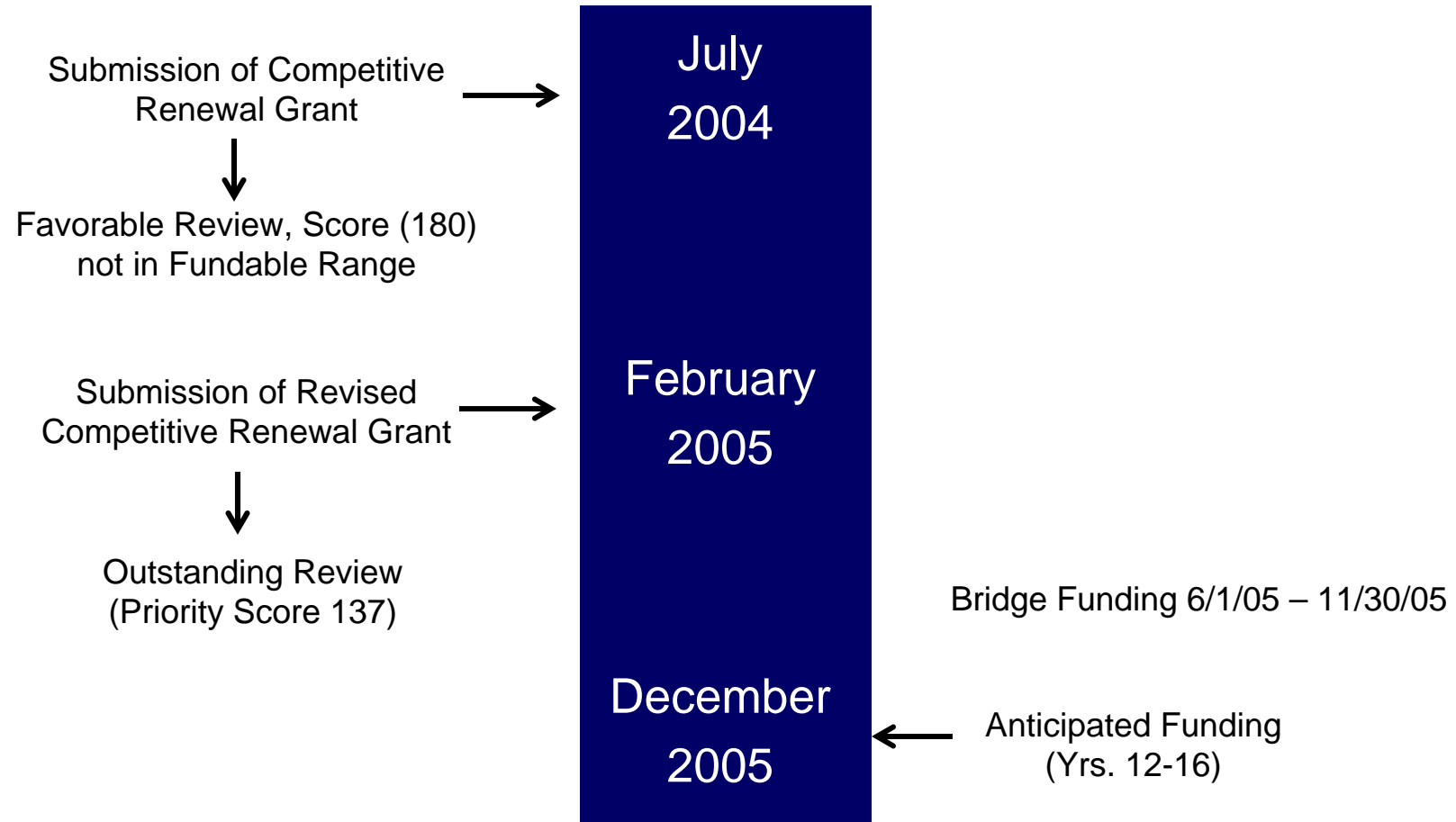
### **REPRODUCTIVE OUTCOMES**

**Mark Krailo, Ph.D.**  
University of Southern California

### **SECOND MALIGNACIES**

**Louis S. Constine, M.D.**  
University of Rochester

# CCSS Competitive Renewal & Funding



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## 2005 – 2010 Competitive Renewal

### Specific Aims

1. **Maintain** the strong and productive resource of the CCSS through continued follow-up of the initial population (diagnosed between 1970-86)
2. **Enhance** the resource by recruiting individuals diagnosed between 1987-99.
3. **Promote and facilitate** the use of the CCSS Resource

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## Highlights since last meeting

### **Competitive renewal grant (Priority score 137)**

Continued Follow-up  
Expanded Cohort

### **Manuscripts published/in press (n=19)**

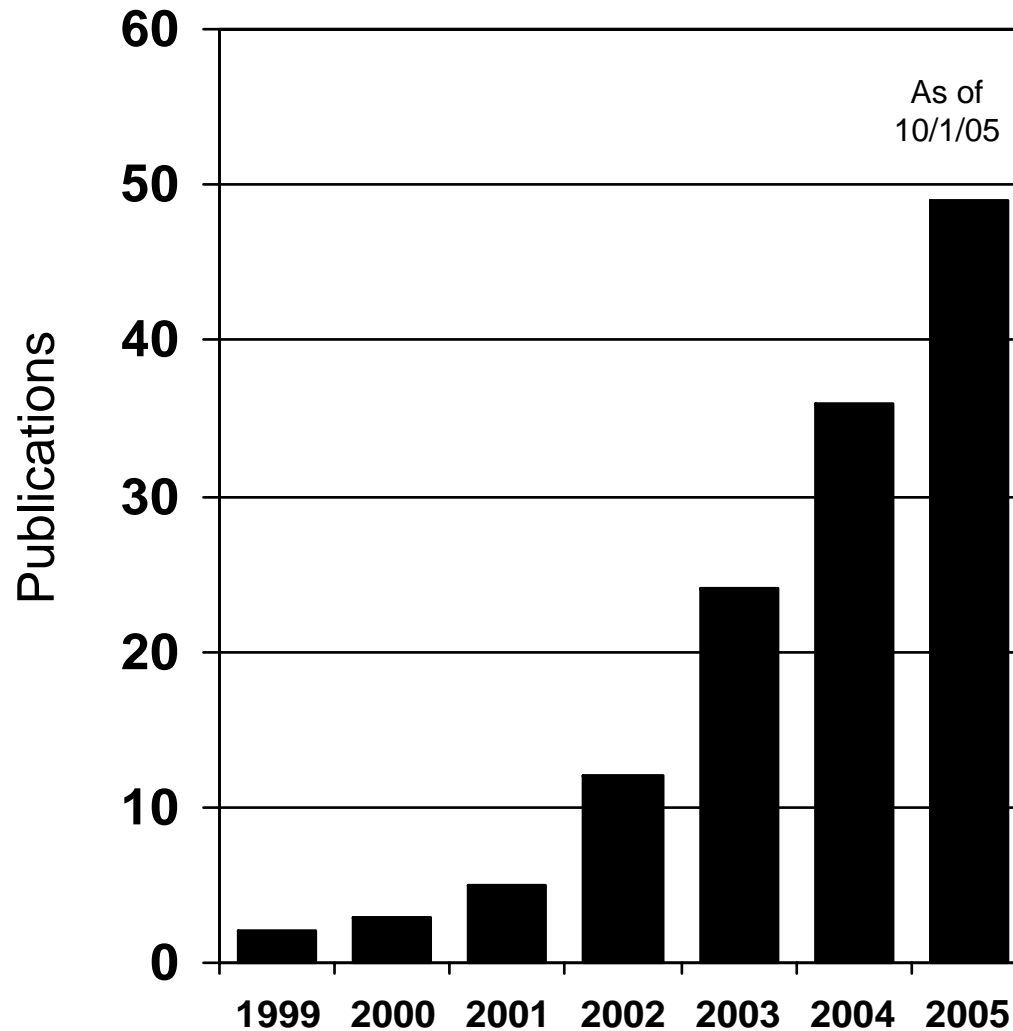
JCO (6)	Lancet	JCEM
Ann Intern Med (2)	Cancer (3)	PBC
Br J Cancer	CEBP	Others

### **Abstracts presented (n=16)**

ASCO (5)	SIOP
ASPHO (3)	AACR
ES (2)	Others

# Cumulative Number of Peer-Reviewed Publications

(2005 reflects published and in press as of Oct. 1, 2005)



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## CCSS as a Resource – U24 Grant

As of July 2005:

- 14 Externally-funded grants
  - 6 NIH
  - 8 Non-governmental agencies/foundations
- Total funding of external grants - \$9,000,000

Currently pending:

- Submitted to NIH (n=1)
- Submitted to LAF (n=4)
- NIH in preparation (n=2)

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## CCSS as a Resource – U24 Grant

Since completion of baseline data collection:

82 investigators contacted CCSS (no previous association with CCSS)

33 (40%) were not from a CCSS participating institution

56 (68%) utilized the resource

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## Sample collection and banking

### Buccal Cells

5795 Banked Samples

46% Response Rate

Utilization (GST/XRCC1, Leptin, GST/SOD/NQ01/CBR)

Quality/Quantity

### Peripheral Blood - LCLs

206 Banked Samples

52% Est. Response Rate

Utilization (Hendrickson, pilot DNA-PK; Nikiforov, R01)

### Tumor Tissue

198 Banked SMN Samples



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# Childhood Cancer Survivor Study

[www.cancer.umn.edu/ccss](http://www.cancer.umn.edu/ccss)

Overview of the project

Publications

Abstracts

Questionnaires

Cohort Characteristics

Biologic Specimens

Supplemental Materials

Newsletters

# CCSS Organizational Structure

## CONTRIBUTING INSTITUTIONS & INVESTIGATORS

### WORKING GROUPS

Second Malignancies	Chronic Disease
Reproductive	Prevention & Control
Genetics	Neurologic/Neuropsychologic
Epidemiology/Biostatistics	Chemotherapy/Radiation/Surgery

STEERING COMMITTEE  
Principal Investigator (U24)  
Working Group Chairs  
NCI Collaborators  
Facility Directors

### SUPPORT FACILITIES

Coordinating Center  
Statistical Center  
Radiation Physics Center  
Bio-Pathology Center  
Molecular Genetic Bank

EXTERNAL ADVISORS

RESOURCE ACCESS &  
UTILIZATION COMMITTEE

EDUCATION COMMITTEE

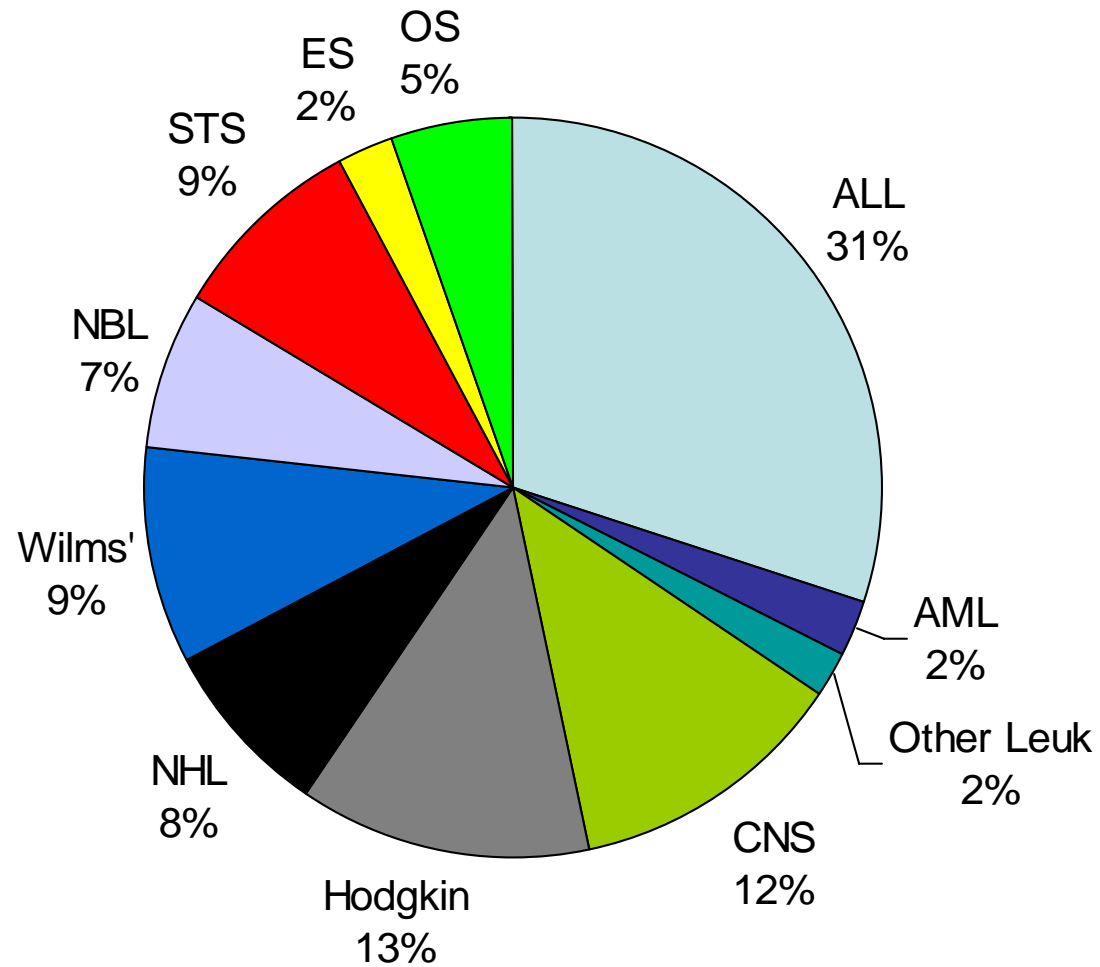
ANALYSIS & PUBLICATIONS  
COMMITTEE

**CCSS**

CHILDHOOD CANCER SURVIVOR STUDY

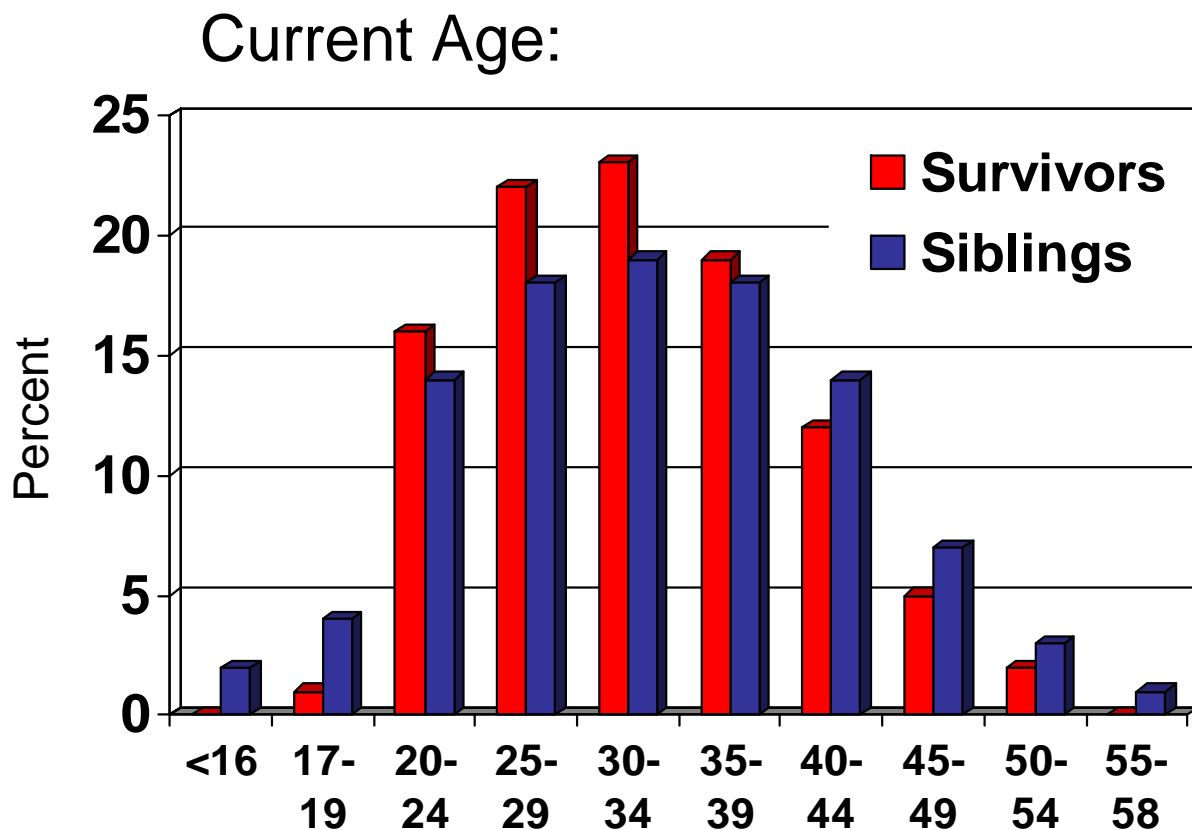
# CCSS as a Resource – U24 Grant

Current Cohort Under Active Follow-up (n=10,928)



# CCSS as a Resource – U24 Grant

Current Cohort Under Active Follow-up (n=10,928)



Sex:

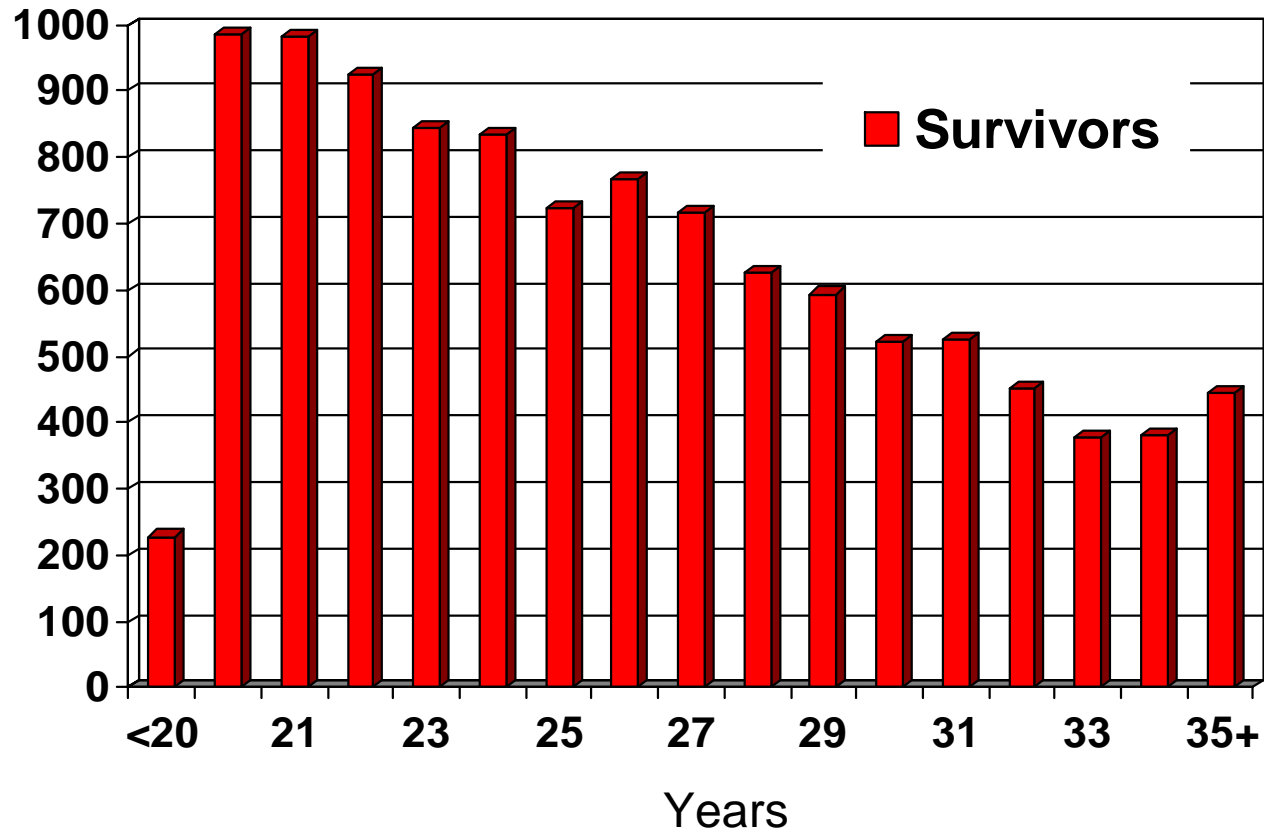
Survivors  
Females (48%)  
Males (52%)

Siblings  
Females (52%)  
Males (48%)

# CCSS as a Resource – U24 Grant

Current Cohort Under Active Follow-up (n=10,928)

## Time Since Diagnosis:



## Race:

White, NH	87%
Hispanic	5%
Black, NH	5%
Native Am.	<1%
Asian/PI	1%
Other	1%

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# Transition of PI and Coordinating Center Minneapolis to Memphis

## Strategy

- Establish coordinating center in Memphis to run parallel with Minneapolis.
- Allow 3-6 month overlap in activities before transferring functions.
- Utilize increased personnel to enhance productivity

## Timeline

- Space to house CCSS available - February 2006
- Begin recruitment of staff - November 2005
- Final transition completed between July - November 2006

## Considerations

- Study Participants (Current Cohort, Expanded Cohort)
- Web Site
- Project Director and Staff

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## Future Meetings

- Coordinate with Niagara-on-the-lake
  - Facilities / location
  - Limit on size of Niagara meeting
- For alternating years – CCSS meeting in Memphis
  - Consider expanding to allow data presentations and invited speakers
  - Abstract submission
- Steering Committee Meetings - every six months

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## Study Status Updates

Coordinating Center

Data and Statistical Center

Radiation Physics Center

Bio-Pathology Center

Molecular Genetics Bank

Education Committee

Publications Committee

Mertens

Leisenring

Stovall

Hammond

Davies

Hudson

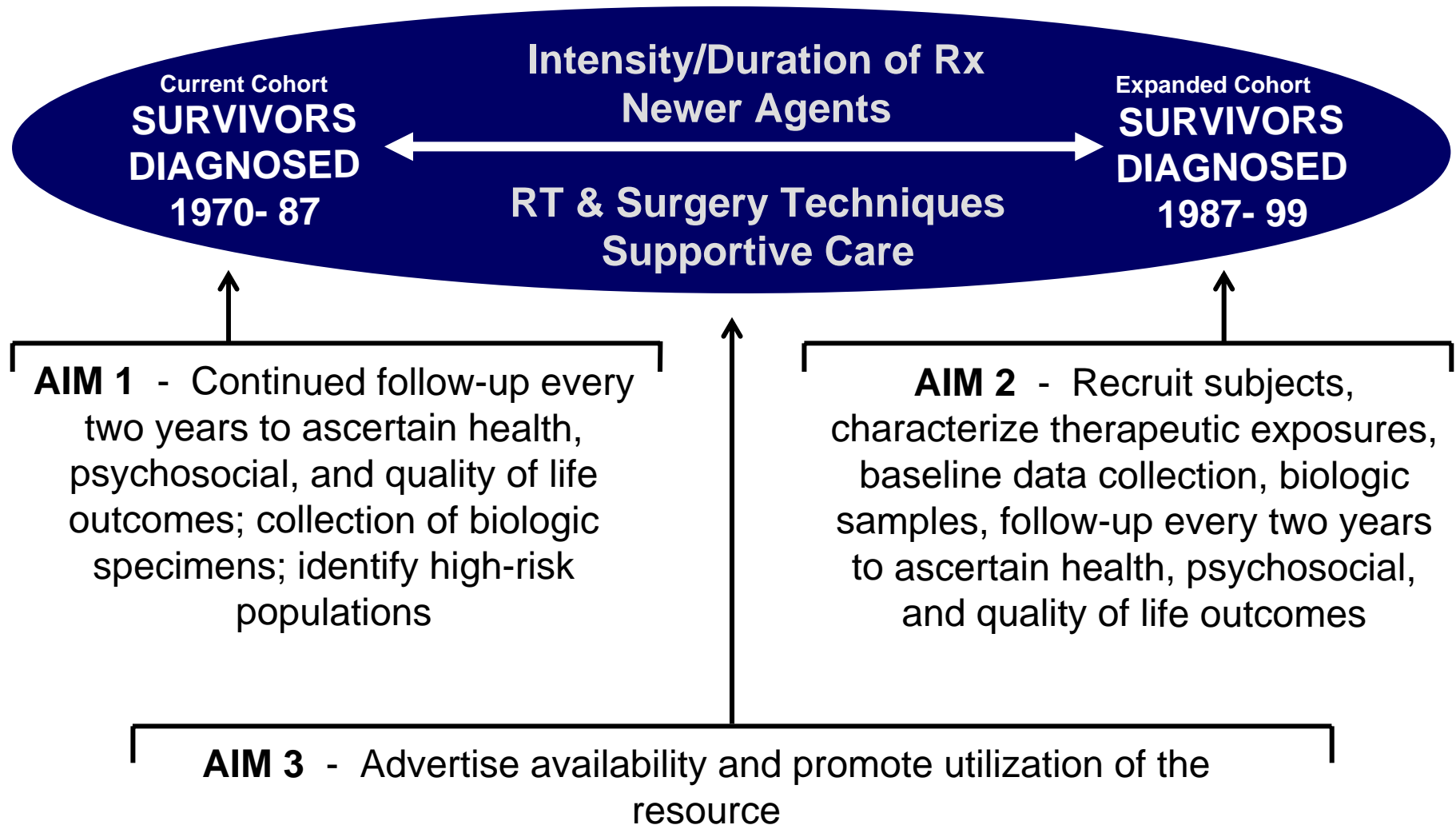
Meadows



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## **Objectives for the 2005-2010 Funding Period**

# 2005 – 2010 Competitive Renewal



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## 2005 – 2010 Competitive Renewal

Specific Aim 1 - Maintain the strong and productive resource of the CCSS through continued follow-up of the initial population (diagnosed between 1970-86):

- Ascertain and characterize occurrence of health-related outcomes and quality of life
- Investigate genetic susceptibility and gene-therapy interactions
- Maintain follow-up through tracing
- Validate selected outcomes
- Identify high-risk populations to aid future cancer control activities

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# CCSS as a Resource – U24 Grant

Factors Influencing the Available Cohort

## **Mortality:**

14% of the eligible cohort has died (2878 deaths)

## **Retention Rate:**

Drop-out rate is approximately 1% per year

## **Participation:**

80-85% on follow-up surveys

## **Lost to Follow-up:**

1-2% at each survey contact

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# CCSS as a Resource – U24 Grant

## Issues to be Considered

### **Existing Data:**

Overlap, duplication with other analyses  
Biostatistical support

### **Interaction with Cohort:**

Continually assess burden on participants  
Follow-up2 Survey

### **Biological Samples:**

Participation rates  
Utilization of the material

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## 2005 – 2010 Competitive Renewal

Specific Aim 2 - Enhance the resource by recruiting individuals diagnosed between 1987-99.

- Recruit and follow an additional 14,800 five-year survivors
- Enrich the recruited cohort with respect to ethnic/racial minorities and disease/treatment groups of greatest interest
- Collect selected baseline and follow-up outcomes information to ensure comparability to the initial cohort
- Enroll 4000 siblings of survivors
- Collect biologic samples for molecular genetic studies

# CCSS Expanded Cohort

Estimated Available Survivor Population (n=31,700)

Diagnosis	Est. 5-Yr Survivors / Target #	
Leukemia	10,920	2650
Acute Lymphoid	9390	2000
Acute Myeloid	930	650
CNS	7270	3000
Lymphoma	4480	3500
Hodgkin Disease	1970	1500
Non-Hodgkin	2510	2000
Neuroblastoma	2110	1000
Wilms' Tumor	2030	1000
Soft Tissue Sarcoma	2470	1000
Osteosarcoma	1405	1000
Ewing Sarcoma	965	650

# CCSS Expanded Cohort

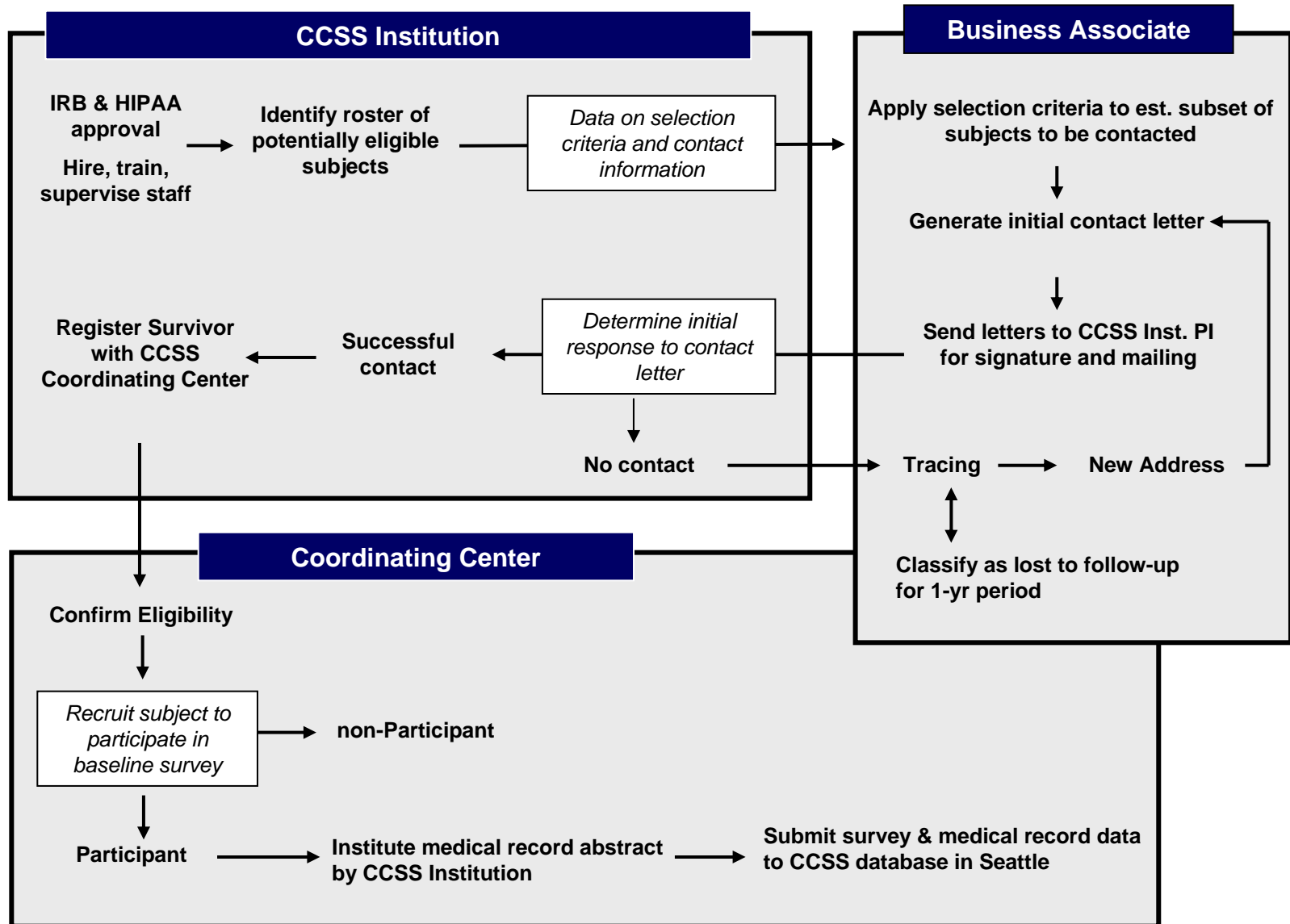
## Selection Factors

Diagnosis	Selection Factors	Weighting Ratio	Total Target # Participants
Acute Lymphoid	Age Dx <1, >10 (intensive Rx)	3:1	2000
Acute Myeloid	None		650
CNS	Race/Ethnicity	2:1	3000
Hodgkin Disease	None		1500
Non-Hodgkin	Race/Ethnicity	2:1	2000
Neuroblastoma	Race/Ethnicity	2:1	1000
Wilms'	Dx 1986-94 (> Doxorubicin)	2:1	1000
Rhabdomyosarcoma	Race/Ethnicity	2:1	1000
Osteosarcoma	Race/Ethnicity	2:1	1000
Ewing Sarcoma	None		650
Retinoblastoma	Race/Ethnicity	2:1	1000

*Race/Ethnicity is ratio of non-white : white*



# Overview of Recruitment Procedures





## 2005 - 2006 DEADLINES

	Institutions	Coordinating Center, Data Center, Business Associate
November		Distribute Material for Institutional IRB submissions
December		Content Established for Baseline Questionnaire and Medical Record Abstraction
January	Identification of Survivor Population Complete	Selection of Recruitment Population
February	Final/Full IRB Approval	Completion of Procedure Manuals
March	Data Management Staff Hired	MRAF Data Entry System Completed and Tested
April		Data Management Training Session
May	Roster of Study Subjects Completed	CATI System Completed and Tested
June		Initiate Recruitment of Study Subjects

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## 2005 – 2010 Competitive Renewal

### Specific Aim 3 - Promote and facilitate the use of the CCSS Resource

- Increase the visibility of CCSS through:
  - Publications
  - Presentations and national/international meetings
  - Links with websites
  - Direct marketing
  - Liaisons with professional societies
- Implementation of a comprehensive public-use data set

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# Resource Access and Utilization Committee

**Chair:** Les Robison

**Charge:** Promote and facilitate the use of the CCSS Resource

**Plans:**

Publication access data base (J. Gurney)

Enhanced visibility

Targeted advertising/promotion

Liaison with other organizations

Meeting: Tuesday 7:30 am - Room E

# Grant Support

Supported by grants from NCI (U24-CA55727)

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# Participating Institutions

St. Jude Children's Research Hospital

University of Minnesota

Denver Children's Hospital

Children's Hospital of Pittsburgh

Stanford University

Dana-Farber Cancer Institute

Children's National Medical Center

M.D. Anderson Cancer Center

Memorial Sloan-Kettering Cancer Center

Texas Children's Hospital

University of California, San Francisco

Seattle Children's Hospital

Toronto Hospital for Sick Children

Children's Hospital of Columbus

Emory University

Roswell Park Cancer Center

Mayo Clinic

Children's Health Care Minneapolis

Children's Hospital of Philadelphia

St. Louis Children's Hospital

Children's Hospital of Los Angeles

UCLA Medical Center

Miller Children's Hospital Long Beach

Children's Hospital of Orange County

Riley Hospital for Children – Indiana Univ.

UAB/Children's Hospital of Alabama

University of Michigan – Mott Children's

Children's Medical Center of Dallas

Fred Hutchinson Cancer Research Center

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# A Resource for Research

- The Childhood Cancer Survivor Study is an NCI-funded resource to promote and facilitate research among long-term survivors of cancer diagnosed during childhood and adolescence.
- Investigators interested in potential uses of this resource are encouraged to visit:

[www.cancer.umn.edu/ccss](http://www.cancer.umn.edu/ccss)

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