

# NHLBI Division of Blood Diseases and Resources

## PACT and BioLINCC Programs

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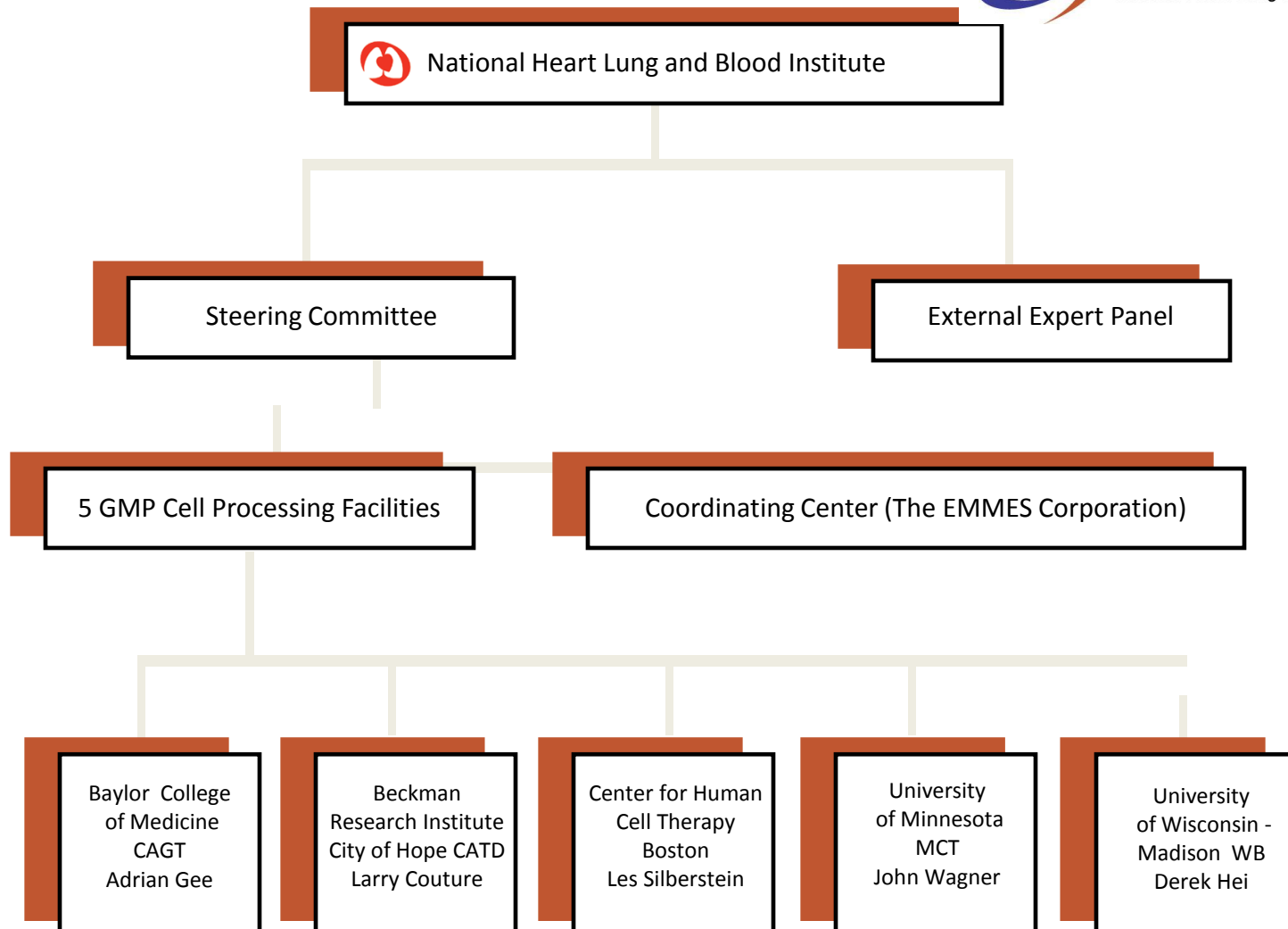
Division of Blood Diseases and Resources  
NHLBI



# PACT Organizational Structure



Production Assistance for Cellular Therapies  
National Heart Lung and Blood Program

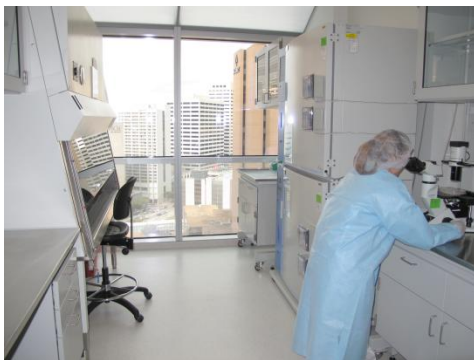


# Production Assistance for Cellular Therapies (PACT)

- Began in September 2003
- Renewed in January 15, 2010
- Number of facilities, scope, and interest expanded

## Objective

Promote the advancement of cellular therapy research in the areas of regenerative medicine as well as develop novel treatments for serious diseases within the fields of cardiac, pulmonary and blood diseases under the scope of the NHLBI



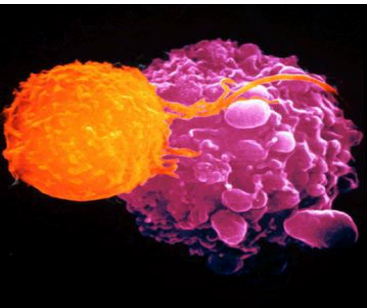
<http://www.pactgroup.net/>



Production Assistance for Cellular Therapies  
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# Scope of PACT

- Products and Services
  - Products that aid in the repair and regeneration of damaged/diseased tissues, organs, and biologic systems
  - Preclinical studies including basic and translational (animal models) work
  - Products of programmatic interest to the Institute and associated with a funded clinical study
  - Proposals possessing procedural advancements to further foster and standardize cell therapies



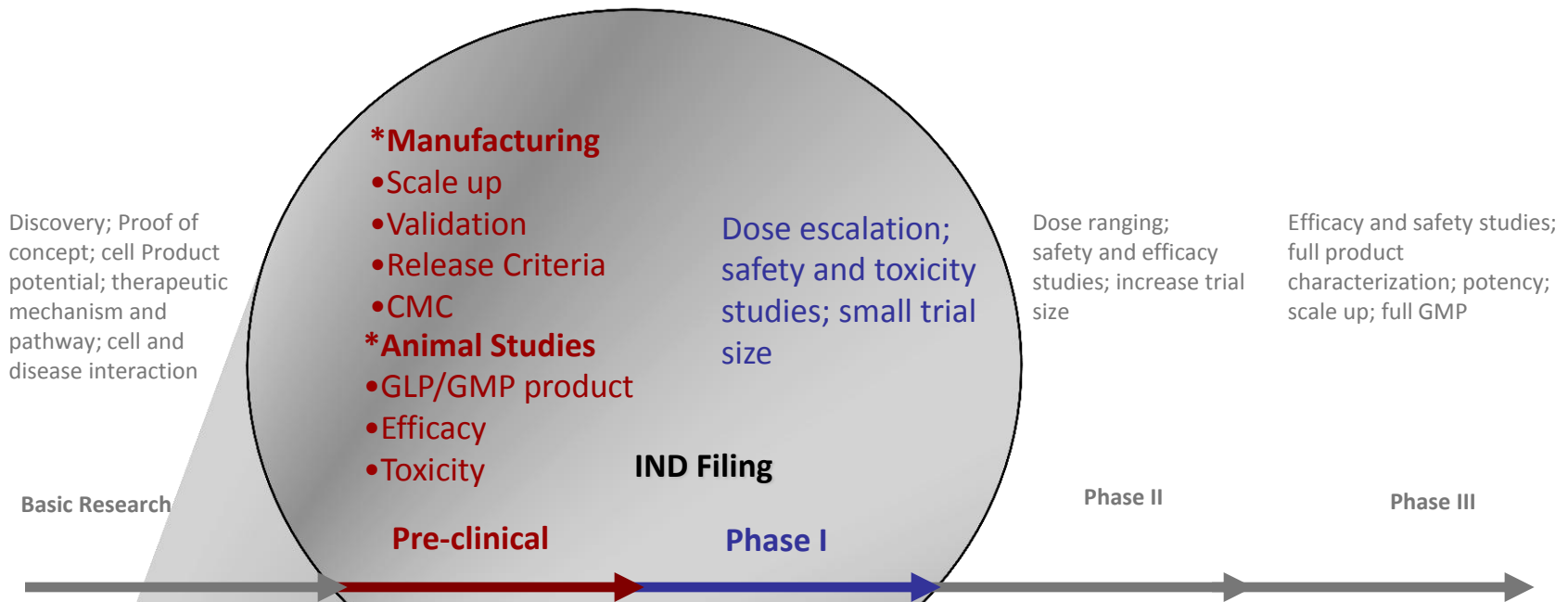
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# Cell Product Manufacturing Capabilities

<i>PROGENITOR CELLS</i>	<i>CELL DEPLETION/CELL ENRICHMENT (BM/PB/UCB)</i>	<i>DENDRITIC CELLS</i>	<i>LYMPHOCYTES</i>
<ul style="list-style-type: none"> <li>• Corneal progenitor cells</li> <li>• HPC</li> <li>• Hepatic progenitor cells</li> <li>• hESC</li> <li>• iPS</li> <li>• Neural progenitor cells</li> <li>• Mesenchymal stem cells</li> </ul>	<ul style="list-style-type: none"> <li>• CD3 depletion</li> <li>• CD34 selection</li> <li>• CD133 selection</li> <li>• CD34<sup>+</sup>/CD3<sup>-</sup></li> <li>• CD56 selection</li> <li>• Counterflow elutriation</li> </ul>	<ul style="list-style-type: none"> <li>• Adenovirally transduced</li> <li>• Apoptotic tumor cell pulsed</li> <li>• Peptide pulsed</li> <li>• Transfected</li> <li>• Tumor lysate pulsed</li> <li>• Tumor-dendritic cell hybrids</li> </ul>	<ul style="list-style-type: none"> <li>• Peripheral blood-derived lymphocytes                             <ul style="list-style-type: none"> <li>◦ Lymphocyte activated killer cells</li> <li>◦ Activated NK cells</li> <li>◦ Invariant NK T cells</li> <li>◦ CD8<sup>+</sup>/CD4<sup>+</sup> T cells</li> <li>◦ CD4<sup>+</sup>/CD25<sup>+</sup> T regulatory cells</li> <li>◦ CTLs (TGFβ, chimeric antigen receptors)</li> </ul> </li> </ul>
<i>LYMPHOCYTES</i>	<i>LYMPHOCYTES</i>	<i>ANTIGEN PRESENTING CELLS</i>	<i>DONOR LEUKOCYTES</i>
<ul style="list-style-type: none"> <li>• Umbilical cord blood-derived lymphocytes                             <ul style="list-style-type: none"> <li>◦ CD4<sup>+</sup>/CD25<sup>+</sup> T regulatory cells</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• EBV-transformed B cell lines (LCLs)</li> <li>• LCLs +/- genetic modification-intermediate product</li> </ul>	<ul style="list-style-type: none"> <li>• Dendritic cells</li> <li>• Leukemic cell lines</li> <li>• Monocytes</li> </ul>	<ul style="list-style-type: none"> <li>• Donor leukocyte infusion</li> <li>• Alloreactive T cell depleted (immunotoxin)</li> <li>• Thymidine kinase (suicide gene)-transduced T cells</li> </ul>
<i>GENETICALLY MODIFIED CELLS</i>	<i>TUMOR VACCINES (translational development)</i>	<i>MASTER/WORKING CELL BANKS</i>	<i>OTHER</i>
<ul style="list-style-type: none"> <li>• Activated T cells</li> <li>• Fibroblasts</li> <li>• Cytotoxic T-lymphocytes (CTLs)</li> <li>• Hematopoietic stem cells (HSC)</li> <li>• Lymphoblastoid cell lines (LCLs)</li> <li>• Mesenchymal stem cells (plasmid or viral vector)</li> <li>• Neural stem cells</li> <li>• Tumor cells</li> <li>• Tumor vaccines</li> </ul>	<ul style="list-style-type: none"> <li>• CLL-directed vaccine (autologous)</li> <li>• Large multivalent immunogen vaccine (autologous)                             <ul style="list-style-type: none"> <li>◦ Breast adenocarcinoma</li> <li>◦ Melanoma</li> <li>◦ Renal cell carcinoma</li> </ul> </li> <li>• Neuroblastoma-directed vaccine</li> </ul>	<ul style="list-style-type: none"> <li>• Artificial antigen presenting cells (K562)</li> <li>• Fibroblasts</li> <li>• Human embryonic stem cells</li> <li>• Mesenchymal stem cells</li> <li>• NK cell lines</li> </ul>	<ul style="list-style-type: none"> <li>• Aseptic filling</li> <li>• B95-8 EBV</li> <li>• Cell culture and expansion</li> <li>• Immune monitoring</li> <li>• Cell manufacturing for large animal models</li> <li>• Potency assay development</li> <li>• Cryopreservation technologies</li> <li>• Monoclonal antibodies</li> <li>• Plasmids</li> <li>• Suspension and adherent cell banks</li> </ul>

# PACT Supported Translational Research



<http://www.pactgroup.net/>

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# NHLBI Biorepository

- Background
  - Managed since 1975 by the Transfusion Medicine and Cellular Therapeutics Branch, Division of Blood Diseases and Resources
  - Includes over 4.9 million biospecimens from 73 unique collections
  - Resides at SeraCare Life Sciences in Maryland



# NHLBI Data Repository

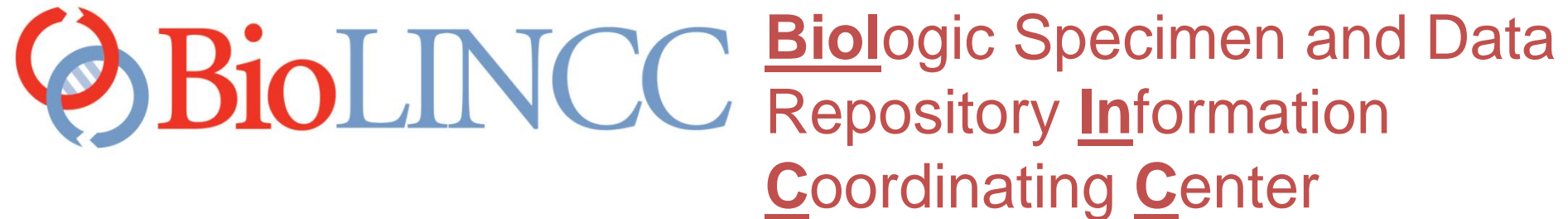
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## Background

- Established in 2000 to share the data sets and documentation obtained from NHLBI funded clinical studies
- Managed by the Prevention and Population Sciences Program in the Division of Cardiovascular Sciences
- Many data sets in the Data Repository have biospecimen collections in the Biorepository



# Increasing the Utility of Stored Biospecimens



- The BioLINCC contract was awarded September 1, 2008 to Information Management Services, Inc. in Silver Spring, Maryland

[Home](#)

## Open Studies

[Study Datasets and Biospecimens](#)[Teaching Datasets](#)[Renew Existing Data Use Agreement](#)[RFA-HL-12-004](#)

## Submitting New Collections

[Register to Submit a Biospecimen Collection](#)[Preparing and Submitting Data Repository Datasets](#)

## About BioLINCC

[FAQs](#)[Glossary](#)[Reference Documents](#)

## Proprietary Studies

## Questions/Comments

## Welcome to the Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC) website!

- [Learn](#) about Open Collections and request processes
- [Request](#) data and/or biospecimens from Open Collections
- [Register](#) study information to submit a new biospecimen collection
- [Learn](#) about requesting biospecimens in the Proprietary Period

## Search for Study Datasets and/or Biospecimens

From here you can search study description pages for studies that meet your criteria and request more information on available data and/or biospecimens. Enter keyword(s) into the "Search For" field below and check the boxes to indicate if you are interested in studies with available datasets, biospecimens, or with both. Leaving the checkboxes blank will return studies with either material type:

Search For: [Common Properties](#)[Material Types](#)[Conditions](#)[Study Type](#)[Period](#)

Filter

- Select All**
- Has Study Datasets**
- Has Specimens**
- Do Not Include Studies with Commercial Use Restrictions**

## Recent News

### New Study: RISE

2011-08-31

A new study, Retrovirus Epidemiology Donor St...

### New Study: LAPS

2011-08-24

A new study, Retrovirus Epidemiology Donor St...

### New Study: WLM

2011-08-02

A new study, Weight Loss Maintenance (WLM), h...

### New Study: OMNI Heart

2011-07-06

A new study, Optimal Macronutrient Intake Tri...

### New Study: P2C2

2011-06-07

A new study, Pediatric Pulmonary and Cardiova...

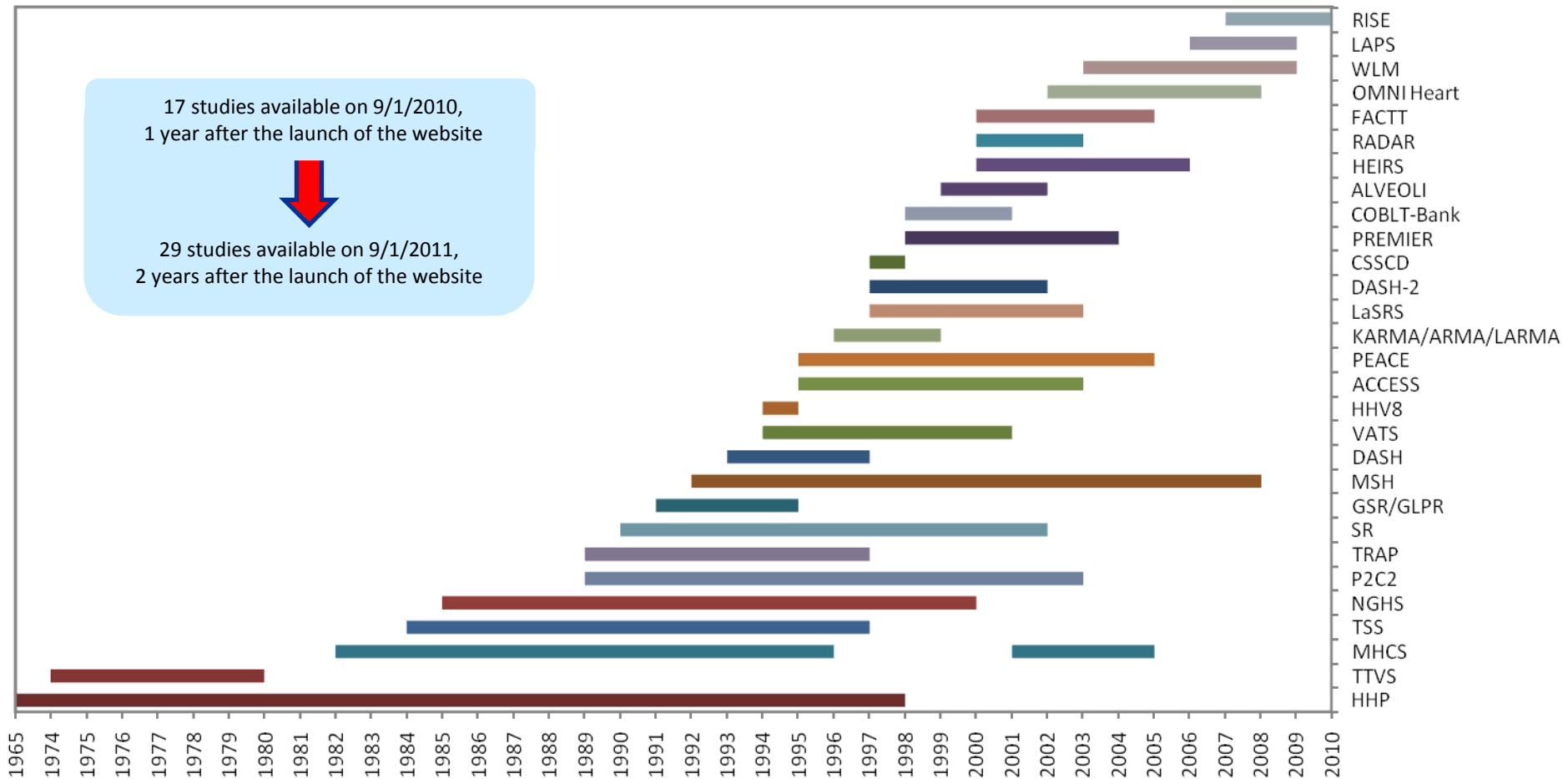
[more news...](#)

# “Open Study” Collections

17 studies available on 9/1/2010,  
1 year after the launch of the website



29 studies available on 9/1/2011,  
2 years after the launch of the website



# Accessing Biospecimens/Data

- The BioLINCC process was designed to encourage applications:
  - A two step application process
    - initial search requiring minimal data
    - formal request requiring details of the research protocol
- The review process was developed pre-BioLINCC:
  - External review committee comprised of three core members & two scientific ad hoc members
    - scientific question
    - appropriateness of the biospecimens & impact on the collection
    - ethical issues

# Summary

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- The NHLBI has centralized two valuable open scientific resources to increase biospecimen and data utilization
  - NHLBI Biorepository
  - NHLBI Data Repository
- Online access to these resources is available on the BioLINCC web site at: [www.biolincc.nhlbi.nih.gov](http://www.biolincc.nhlbi.nih.gov)
- Biospecimen requests are being streamlined to provide a fast and complete review of the research application

# Contact Us

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