

**Alphabet Soup: Trial Funding and Support  
Mechanisms and How to Use Them  
Within the Alliance**

***NCI Community Oncology Research Program  
(NCORP)***

**May 11, 2017**

---

***Worta McCaskill-Stevens, M.D., M.S.  
Director, NCORP***

***Chief, Community Oncology and Prevention Trials Research Group  
Division of Cancer Prevention***

# New Generation of Clinical Trials and Related Research

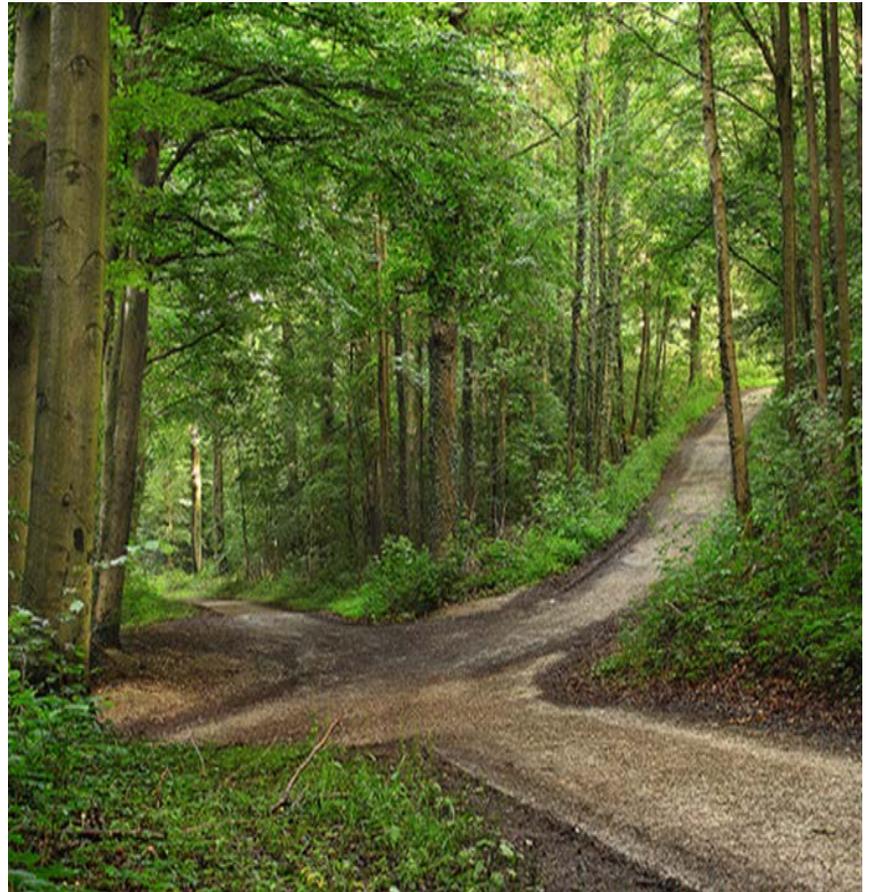
---

## Drivers

**Biology**

**Technology**

**Economic and  
Demographics**



# Challenges to the Physician-Scientist Team

---

- **Demand for oncology services is expected to rise rapidly, driven by aging, growth of the population and improvements in cancer survival rates**
- **The oncology workforce is aging and retiring in increasing numbers**
- **Demand is expected to rise 48% between 2005 and 2020. This translates into a shortage of 9.4 to 15.0 million visits, or 2,550 to 4,080 oncologists—roughly one-quarter to one-third of the 2005 supply.**

# **Biomedical Workforce (BMW) Working Group June 2012 Report Recommendation**

---

- **Different economic and educational drivers affect the training and career paths of the physician-scientist workforce than the PhD workforce**
- **Changing landscape of health care and its effects on academic medical centers will affect future physician-scientist workforce**

# Charge to the Physician-Scientist Workforce (PSW) Working Group

---

- **Develop approaches that can inform decisions about the development of the U.S. PSW**
- **Analyze the size and composition of the PSW; consider impact of NIH funding policies**
- **Assess needs and career opportunities for PS**
- **Identify incentives and barriers to entering the PSW**

# Trial Funding and Support Mechanisms

## Today's Discussion

---

- **Overview: NCORP through year 3**
- **Funding of Trials/Studies**
  - **NCORP Research Bases**
  - **NCORP Community & Minority/Underserved Sites**
  - **Non-NCORP Research Base Members**
- **Other NCI Resources**

# **Brief NCORP Overview**

# NCORP: 3 Components

---

## Research Bases

- Design and conduct multi-center trials in cancer prevention, control, screening and post-treatment surveillance clinical trials and cancer care delivery studies
- Provide scientific and statistical leadership
- Data management, administration, regulatory compliance

## Community Sites

- Accrue participants to NCORP trials/studies (may include providers, organizations) and to NCTN treatment/imaging trials

## Minority/Underserved Community Sites

- Accrue participants to NCORP trials/studies (may include providers, organizations) and to NCTN treatment/imaging trials
- Communities are composed of 30% Minority/Underserved

# NCI Community Oncology Research Program (NCORP) is an Academic/Community Partnership

---

**Clinical Trials** for prevention, control, health-related quality of life, comparative effectiveness, and screening

- **7,527 patients in Year 1 and 2 combined**  
(includes enrollments to QOL sub-studies to Treatment Trials)

**Accrual** to National Clinical Trials Network (NCTN) treatment and imaging trials

- **6,742 patients in Year 1 and 2 combined**

# NCI Community Oncology Research Program (NCORP) is an Academic/Community Partnership

**Cancer care delivery research** focused on patient-provider and organization-level influences on cancer outcomes

Study ID	Study Title	Status
SWOG S1417CD	<i>Implementation of a Prospective Financial Impact Assessment Tool in Patients with Metastatic Colorectal Cancer (n=374)</i>	Activated and enrolling participants Now open to all NCORP sites on CTSU (no longer only SWOG affiliates)
SWOG S1415CD	<i>A Pragmatic Trial to Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention (TRACER)(n = 32 practices and 3960 patients)</i>	Activated and enrolling and participants Open on CTSU
COG ACCL15N1CD	<i>Improving the use of Evidence-Based Supportive Care Clinical Practice Guidelines in Pediatric Oncology (n=450 patients/32 health care providers)</i>	Activated and enrolling participants COG affiliates
Alliance A191402CD	<i>Testing Decision Aids to Improve Prostate Cancer Decisions for Minority Men (n=175)</i>	Approved Awaiting activation at Alliance Will be on CTSU - Looking for additional sites to participate especially those with African American and Native American populations
COG ACCL16N1CD	<i>Documentation and Delivery of Guideline-Consistent Treatment in Adolescent and Young Adult (AYA) Acute Lymphoblastic Leukemia (n=270 patients/ as well as health care provider focus groups)</i>	Protocol under review @ NCI Will be on CTSU

# NCI Community Oncology Research Program (NCORP) is an Academic/Community Partnership

---

Incorporation of **cancer disparities research** into clinical trials and cancer care delivery research

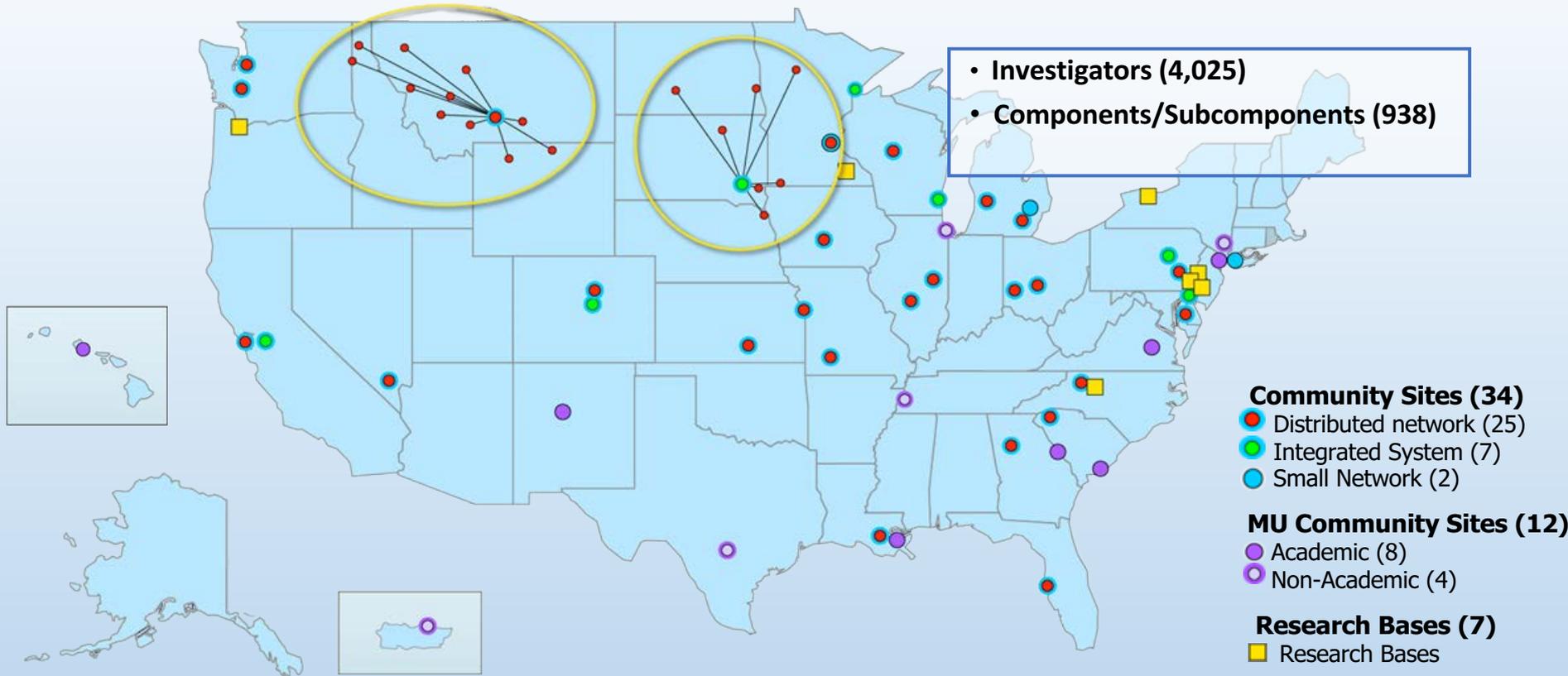
- **Wake Forest U: Improving Resection Rates Among African Americans with NSCLC**
- **Early onset malignancies in 6 cancer in racial/ethnic populations**
  - Breast, colon, prostate, renal, liver, multiple myeloma
- **Expanded demographic and accrual data: DCP 001**

# Precision Medicine NCTN Trials: ALCHEMIST Accrual as of 4/28/17

## Accruals by Organization Type (Swim Lane)

Accruals by Organization Type (Swim Lane)									Name	Accrual
Swim Lane	A15 1216	% of A151216 pts	A081 105	% of A081105 pts	E4512	% of E4512 pts	EA 5142	% EA5142 pts		
LAPS	461	25%	25	24%	9	26%	21	21%	Kaiser Permanente NCI Community Oncology Research Program	99
<b>NCORP</b>	<b>705</b>	<b>38%</b>	<b>39</b>	<b>38%</b>	<b>16</b>	<b>46%</b>	<b>40</b>	<b>41%</b>	Michigan Cancer Research Consortium NCORP	61
ROSTERED	692	37%	40	38%	10	29%	37	38%	Southeast Clinical Oncology Research (SCOR) Consortium NCORP	53
									Georgia NCI Community Oncology Research Program	50
									Metro-Minnesota NCI Community Oncology Research Program	44
									Catholic Health Initiatives NCORP	42
									Heartland Cancer Research NCORP	41
									Pacific Cancer Research Consortium NCORP	29
									Main Line Health NCORP	27
									Wichita NCORP	21
									Stroger Hospital of Cook County Minority Underserved NCORP	19
									Baptist Health System/Mid South Minority Underserved NCORP	15

# NCORP Community Site, MU Community Site and Research Bases Geographic and Organizational Diversity



# ***Funding Mechanisms***

# NCORP Study and Enrollment Funding

---

**Concept & Protocol Development**

**Funding from NCORP Research Base Grant**

- Study Development
- Statistical Support
- Committee Support
- Data Safety Monitoring Committee(s)
- Auditing
- Data Analysis

**Reimbursement for Patient Enrollments**

**NCORP Community Sites**

Annual grant award funds cover enrollments

**LAPS, Main Members, Affiliates, etc.**

Per case reimbursement from Research Base grant

# Investigator-Initiated Grants in NCORP

---

- **Must be conducted via the Research Base**
- **Federally grants are reviewed at the protocol level**
- **Non-Federally funded grants are reviewed at the concept level**
- **NCI has recently released guidance for the following:**
  - **Time-line from grant approval to submission of protocol**
  - **Strategies to obtain feasibility and level of interest input from NCORP community and academic investigators**

# Feasibility of Omega-3 Supplementation for Cancer-Related Fatigue (Peppone, R03 CA 175599)

---

## Primary Aims:

- 1) Collect preliminary statistical data (mean changes & standard deviations) on two Omega-3 supplementations vs. placebo for reducing CRF

## Secondary Aims:

- 1) Determine adherence and adverse events, and
- 2) Collect preliminary statistical data on possible mechanisms of action to inform the design of future trials

**URCC 13091 – NIH funding was needed to purchase the agent**

# **S1415CD A Pragmatic Trial to Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention For Febrile Neutropenia**

---

## **Primary Aim:**

**To compare the use of primary prophylactic colony stimulating Factor according to recommended clinical practice guidelines among pts registered at intervention components vs. usual care components**

## **Secondary Aims:**

**To determine the neutropenia rate among low risk patients**

**PCORI Funding**

# **A221505: Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation with Breast Reconstruction**

---

**Primary Objective: To evaluate whether the reconstruction the complication rate at 24 mos. post radiation is noninferior with hypofractionation compared to standard fractionation**

**Secondary Objective: To evaluate the incidence of acute and late radiation complications**

**Use of IROC– mechanism- supplement to NCTN U-24**

# BIQSFP Funding



BIOMARKER, IMAGING  
& QOL STUDIES  
FUNDING PROGRAM

- **Goal:** Enhance the scientific quality of NCI-funded clinical trials by improving prioritization, funding and standardization of associated biomarker and quality of life studies
- **Initiative 1:** Assure that **adequate funding** is available for clinical trials involving biomarkers, imaging, and quality of life
- **Initiative 2:** Establish **quality control standards** for laboratory assays and imaging procedures used in association with NCI-funded clinical trials

# 2017 Eligibility



- **NCTN Groups and NCORP Research Bases**
- **Phase 2 ( $\geq 100$  patients) and 3 treatment clinical trials with integral or integrated biomarker or imaging or QOL/PRO studies**
- **Phase 3 Cancer Prevention clinical trials with integral or integrated biomarker or imaging studies**
- **Randomized Symptom Science trials with efficacy endpoints**
- **Cost-Effectiveness Analysis (CEA) studies: randomized phase 3 treatment or prevention clinical trial with a comparator arm or a symptom science/supportive care clinical trial with a comparator arm.**

# Funding & Review

Biomarker  
Imaging  
QOL  
CEA

---

Integral

Integrated

---

NCI Steering Committee evaluation

---

CTROC prioritization and funding approval

---

Periodic CTAC review

# NCORP Launch to Present: Accrual Successes

---

## **A221303: Early Palliative Care vs Standard Oncology Care**

- **400+ patients**

## **Alliance 221304 - Phase III Placebo-Controlled, Randomized Three-Arm Study of Doxepin and a Topical Rinse in the Treatment of Acute Oral Mucositis Pain in Patients Receiving RT with/without Chemotherapy**

- **272 patients**

## **ECOG/ACRIN 4112 – Prospective Study of Magnetic Resonance Imaging and Multi-parameter Gene Expression Assay in DCIS**

- **362 patients**

## **Additional NCI Resources**

# NCI Resources

---

- **NCORP Program Directors**
  - **Diane St. Germain and Iman Martin**
- **Coverage Analysis and Partnership with CMS**
- **NCORP CCDR Landscape Data**
- **NCORP will have trial specific data about accrual (Log)**
- **<https://ncorp.cancer.gov/>**

# Summary from NCI DCP Cancer Prevention Think Tank Published in AACR Cancer Prevention Research

## Identifying and Creating the Next Generation of Community-Based Cancer Prevention Studies: Summary of a National Cancer Institute Think Tank

Worta McCaskill-Stevens, Deborah C. Pearson, Barnett S. Kramer, Leslie G. Ford, and Scott M. Lippman

DOI: 10.1158/1940-6207.CAPR-16-0230 Published February 2017

[Article](#)

[Figures & Data](#)

[Info & Metrics](#)

 [PDF](#)

### Abstract

In late 2015, the NCI Division of Cancer Prevention convened cancer prevention research experts and stakeholders to discuss the current state of cancer prevention research, identify key prevention research



February 2017

Volume 10,

Issue 2

[Table of Contents](#)

[Table of Contents \(PDF\)](#)

[About the Cover](#)

[Index by Author](#)

# **Working Groups**

---

**Radiation Oncology**

**Adolescent and Young Adult**

**Non-Oncology Specialists**

**Disparities Integration**

# Non-Oncology Specialists WG GOALS

---

- **Create and share strategies to engage primary care physicians and other non-oncology specialists** (e.g. gastroenterologists, gynecologists, primary care practitioners) and connect with organizations (e.g. NMA, AAFP, etc.)
- Support these connections **with researchers and other relevant organizations**
- Invite member representatives from these organizations to act as **champions for cancer prevention research trials** across their organizations.

***Thank you!***

# SC Concept & BIQSFP Review and Approval: Genesis of a Protocol

\*Integral BIQSFP submitted and reviewed by SC along with initial concept and concept revisions

**Concept Approval S.C.**

**3-month deadline**

Study Team/Research Base develops protocol responding to outstanding issues from the concept review

Integrative BIQSFP submitted and reviewed by SC

FDA submit in parallel if applicable

Submits to DCP

DCP reviews  
Sends response  
Approve, Revise/resubmit, disapproval

**2-month deadline**

Revise, responding to review comments  
Submit to DCP

Central IRB Review

Protocol is activated by research base

FDA finalization  
Intervention prep

Accrue!

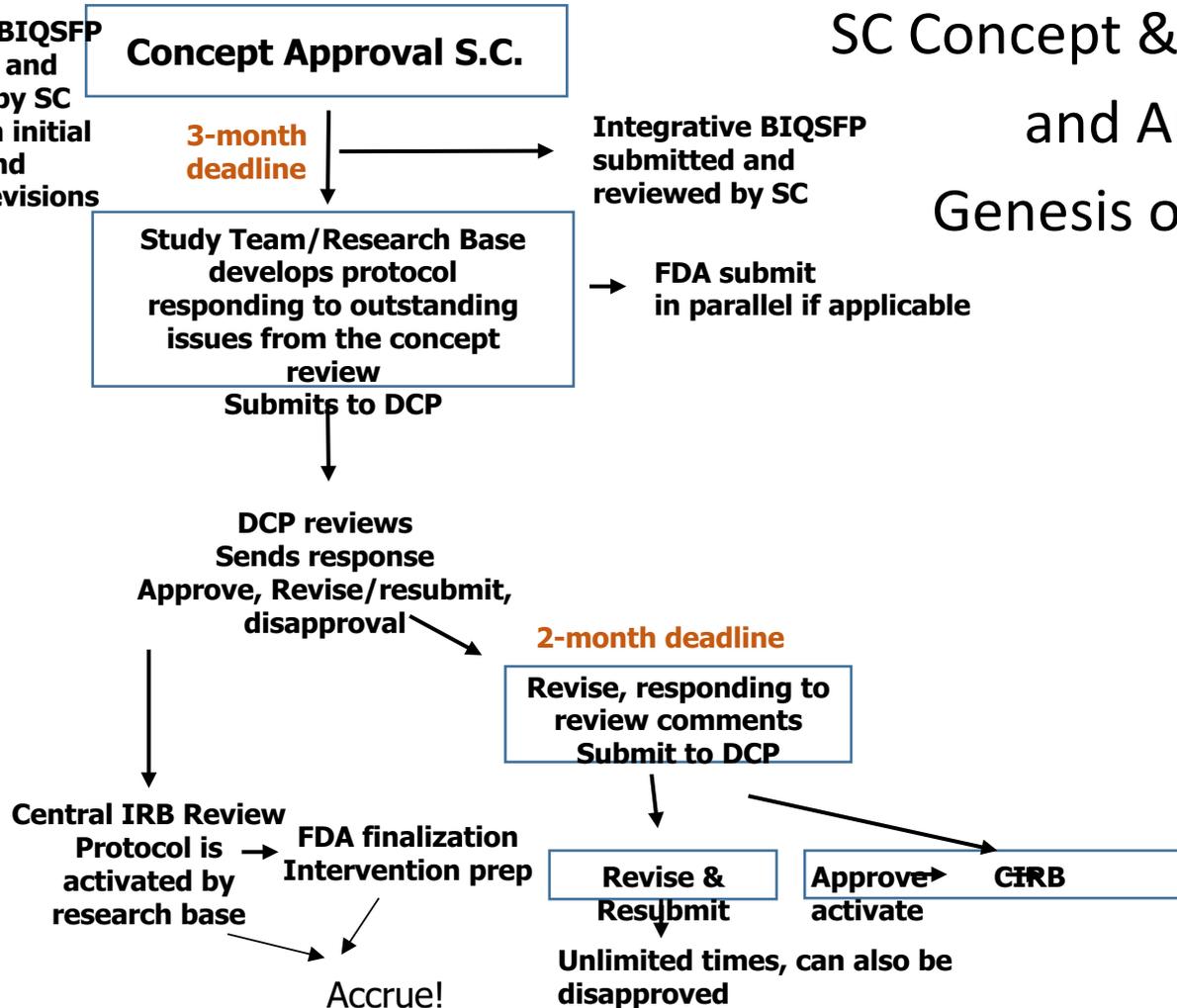
Revise & Resubmit

Unlimited times, can also be disapproved

Approve & activate

CIRB

Delays can occur from:  
CIRB review pending  
CIRB requested changes



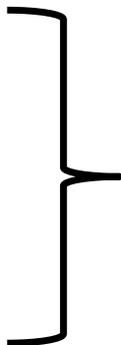
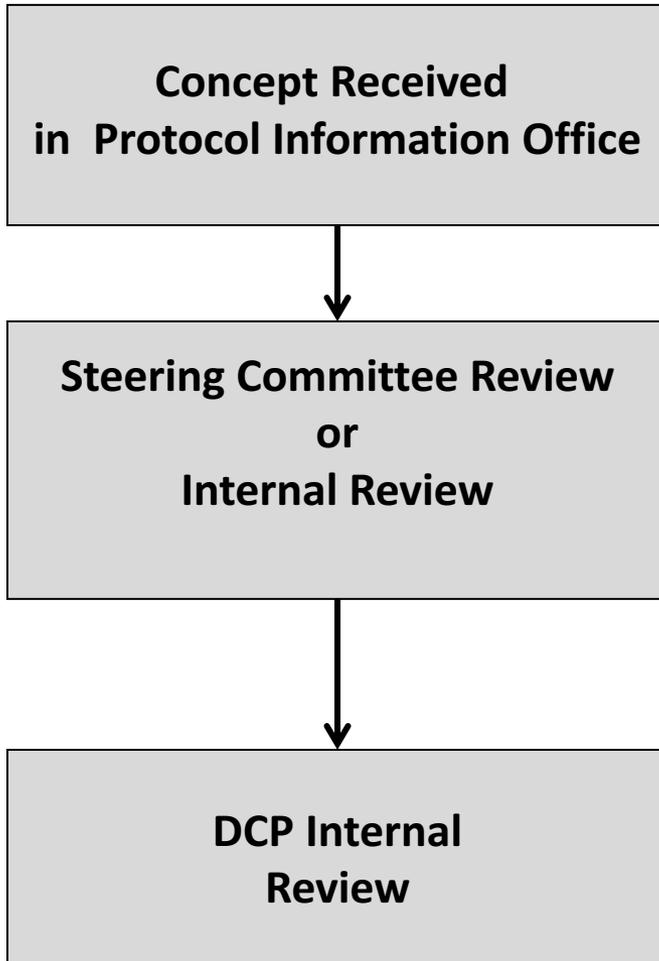
# Evaluation of NCORP Research Concepts

---

- **The concept is the most important document from which the scientific merit for an idea is evaluated**
- **All concepts are reviewed internally**
- **NCI has a Steering Committee (SC) review process for disease and nondisease concepts**
- **Following a concept approval by a SC, the protocol development is managed internally**

# NCORP Concept Review

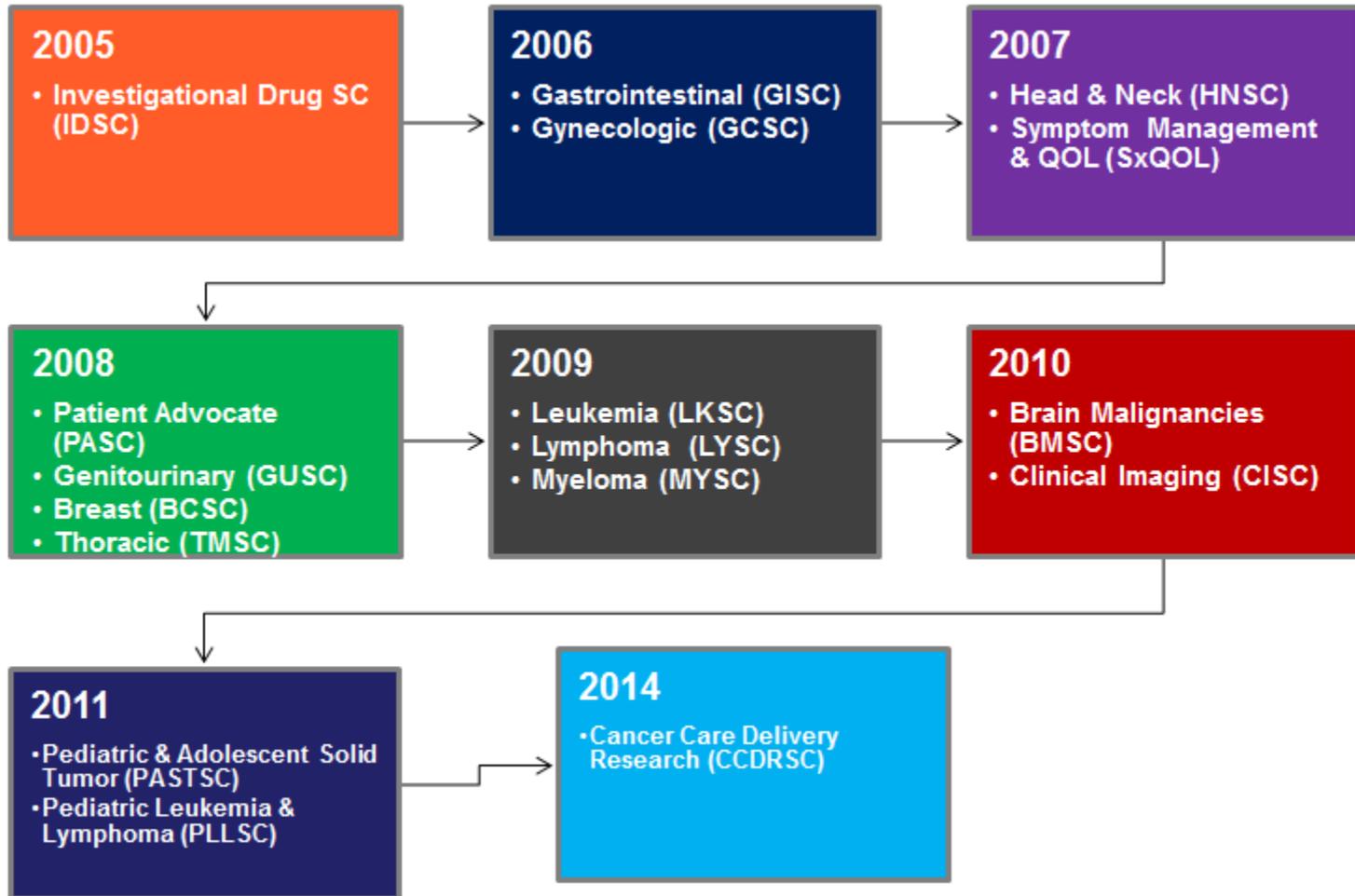
---



## Chairperson, Reviewers and PIO Team

Medical Officers  
Nurse Consultants  
DCP Biometry  
Experts from DCCPS, DCTD, CRCHD  
Other Expertise: NIH, NCI CCR,  
Extramural Community

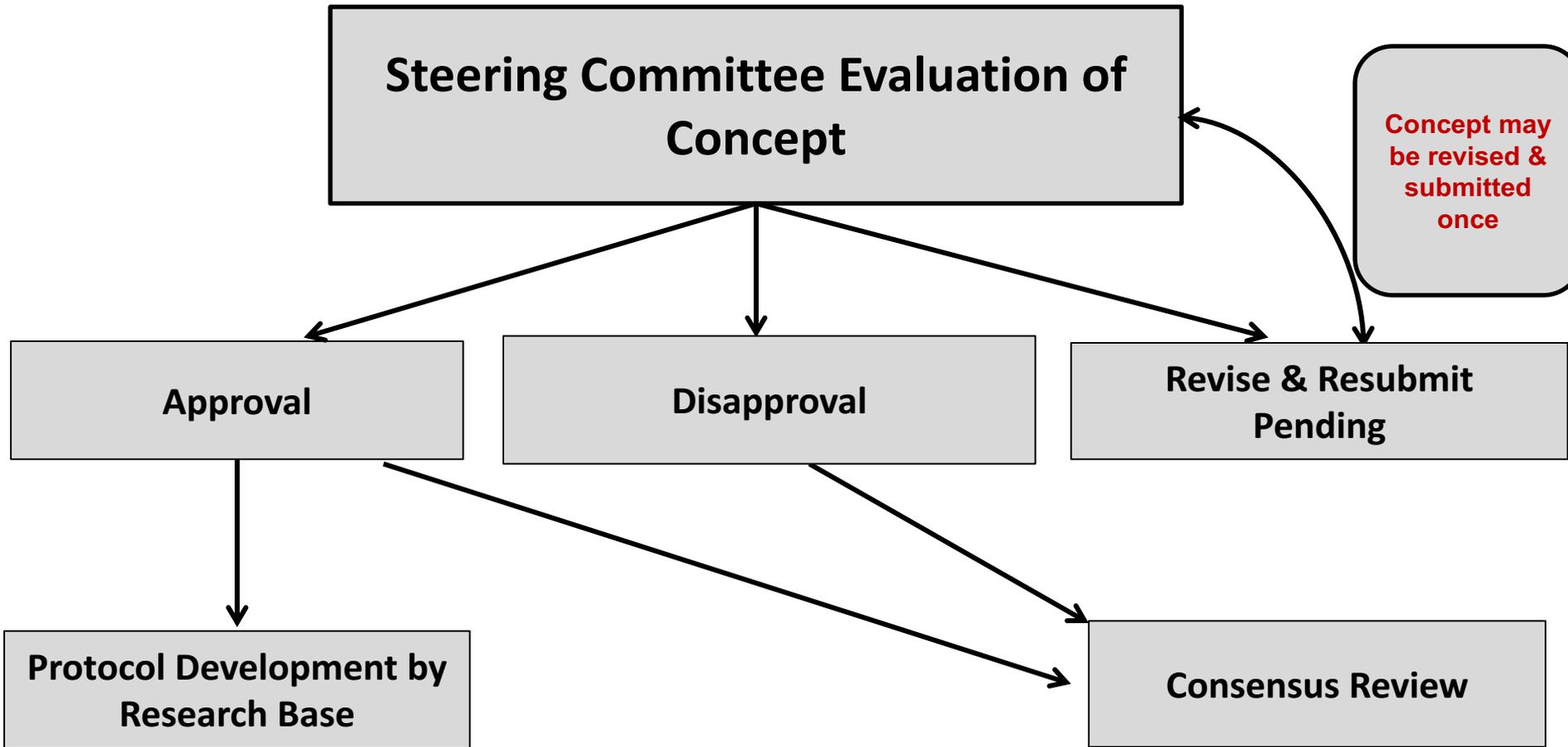
# NCI Coordinating Center for Clinical Trials: Scientific Steering Committees



- Symptom Management & QOL
- Cancer Care Delivery
- Clinical Imaging
- Breast

# Concept Evaluation Process

---



# What Does Not Go to the Steering Committees?

---

- Longitudinal studies, surveys, cancer prevention
- Pediatric cancer control
- Studies  $\leq 100$  participants
- Research studies for which there is no established scientific SC
- Studies reviewed & funded by Federal Agencies
  - Investigator Initiated Studies are reviewed at the protocol level
- Phase 0 and 1 Trials

# Protocol Review

---

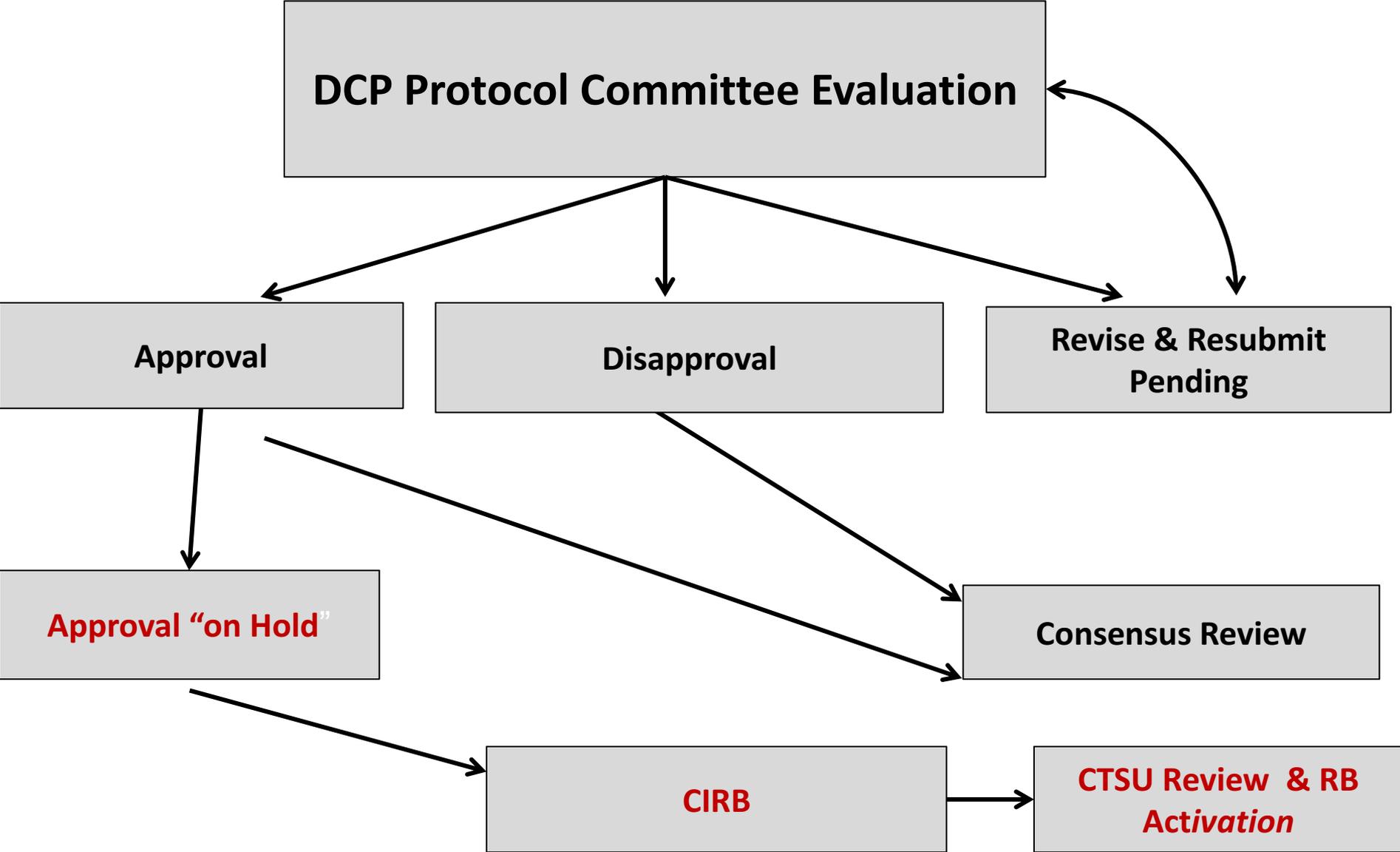
- Includes all information and procedures necessary for conducting a successful trial/study
- Assesses IND status, credits, rosters, accrual plans, non-federal funding
- Evaluates the inclusion of scientific input from the concept review

A lot has happened “behind the scenes”



# Protocol Evaluation Process

---





# Investigator Initiated Grants

- **Must Come through the Research Bases**
- **Reviewed at the Protocol Level**
- **No phase III RCTs for Prevention**

***The world we created today has problems which cannot be solved by thinking the way we thought when we created them.....Albert Einstein***

---

# Minority Enrollment to NCI Cooperative Group Clinical Trials

