

Alliance Adopts New Study Concept Review Process

Submission to the Study Concept Review Committee (SCRC) is a critical step in the process of receiving approval for opening a study within the Alliance for Clinical Trials in Oncology. The concept should provide sufficient information to establish the scientific rationale for the proposed study, describe the study methodology, and support the feasibility of conducting a successful study. After the concept is approved, the full protocol is developed and submitted to the National Cancer Institute (NCI) for review and approval before the study can open.

The SCRC is composed of a rotating 30-member reviewer pool, including 27 scientific reviewers and three patient advocates; seven standing members consisting of the Alliance Group Chair, Vice Chair and the five Program Principal Investigators (representing Central Protocol Operations, Translational Research, Cancer Control, Prevention and Health Outcomes, American College of Surgeons Clinical Research Program, and Statistics and Data Management); and two statisticians. There are 17 voting members – 10 selected from the reviewer pool (nine scientific, one patient advocate), plus the seven standing members. Of the rotating 30-member reviewer pool, 10 members will be voting members at any one time, and will attend each meeting and vote on all concepts; the other 20 will be available to review, if needed. All committee members will have voting privileges during only one year, except that they always vote on any concept they review.

Currently, there are 10 reviewers from each legacy Group (ACOSOG, CALGB and NCCTG) who were nominated by their legacy Group Chairs, and will serve a one- to three-year term, allowing one-third of the committee to turn over each year during the Alliance's three-year transition period ending in 2014. Moving forward, future members may be nominated by a committee formed by outgoing members and approved by the Executive Committee. Future reviewers will all serve a three-year term.

Concept Submission Process

- All Alliance concepts should be sent to the Alliance Study Concept Review Committee (alliance.concepts@calgb.org), including Cancer Control, Prevention and Health Outcomes (CCPHO), retrospective data analyses, and tissue-based studies.
- Concepts should be submitted by the Committee Chair, and the Committee Chair should provide updated priority ranking with each submission.
- Non-Alliance concepts also will be accepted.
- Academic and Community Cancer Research United (ACCRU) concepts will be handled separately.
- Prior to submission, all concepts require sign-off from:
 - committee statistician
 - committee chair
 - chairs of committees contributing a scientific component
- Submission deadlines will be two weeks prior to the next scheduled review meeting.
- Concepts should be discussed with the assigned committee faculty statistician no later than two weeks prior to submission deadline.
- It is expected that concepts will have been shared with CCPHO, Pharmacogenomics & Population Pharmacology (PPP), and modality committees (e.g., imaging) prior to submission, to allow them to suggest a collaboration, if applicable.
- Concept review committee will meet monthly.
 - Late submissions are unfair to both protocol operations office and to the reviewers.
 - Conflict of Interest forms must be available prior to concept review.

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More About New Study Concept Review Process

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- Committee Chair and/or Study Chair or their designees must be on call to present concept (5 min) and answer questions (5-10 min), but will be excused for closed discussion.
- Letter from Committee Chair with submission is no longer needed.

Concept Review Process / Voting

- Voters score concepts using the Alliance rubric below. Scores indicate Alliance-wide prioritization.

Categories

- **Clinical impact** = changes standard of care or produces new significant biological insights
- **Overall feasibility** = ease of accrual, adequate resources for level of difficulty
- **Level of innovation** = does this study introduce something new?
- **Coop group relevance** = extent to which study is best done in cooperative group setting?
- **Relative importance** = overall importance in comparison to other Alliance studies in development

Scoring

- **1** = 80% of in development studies are higher priority or falls within bottom 20% of in development studies
- **2** = 60% of in development studies are higher priority
- **3** = 40% of in development studies are higher priority
- **4** = 20% of in development studies are higher priority
- **5** = equal to top 20% of in development studies are higher priority
- Executive Committee (EC) may decline to score if insufficient information is provided.
- Meeting minutes and scores will be communicated to SCRC, disease/modality committees and Study Chair.
- Concepts in top three-fourth of scores (Alliance-wide) will be considered approved and moved forward, possibly with required changes.
- Concepts scored in the lowest quartile of Alliance protocols will be forwarded to EC.
- Study Chair and Committee Chair will be notified of bottom quartile score and provided with review committee comments.
 - If EC disapproves concept, the decision is final and no re-submission will be allowed.

- Either EC or SCRC may stipulate changes that can be monitored by the Protocol Coordinator (PC) or Executive Officer (EO) but do not require re-submission.
- Either EC or SCRC may stipulate changes with require re-submission to SCRC. Only one re-submission is allowed.

Alliance Study Concept Review Committee

Debra Barton, RN, PhD, *Mayo Clinic*
Isabelle Bedrosian, MD, *MD Anderson Cancer Center*
Amylou Dueck, PhD, *Mayo Clinic Arizona*
Bret Friday, MD, PhD, *Essentia Health Cancer Center*
Matthew Goetz, MD, *Mayo Clinic*
David Grinblatt, MD, *NorthShore University HealthSystem-CCOP*
Axel Grothey, MD, *Mayo Clinic*
Nathan Hall, MD, PhD, *The Ohio State University Medical Center*
Andrew L. Himmelstein, MD, *Christiana Healthcare Services*
Aminah Jatoi, MD, *Mayo Clinic*
John Kennedy, MD, *DeKalb Surgical Associates*
Adam Kibel, MD, *Washington University School of Medicine*
George P. Kim, MD, *Mayo Clinic*
Robert S. Krouse, MD, *Southern Arizona Veterans Affairs Health*
Shelly Kuhlmann
Richard Larson, MD, *University of Chicago*
Carisa (Huong) Le-Petross, MD, *MD Anderson Cancer Center*
John Leonard, MD, *Weill Medical College of Cornell University*
Sumithra Mandrekar, PhD, *Mayo Clinic*
Howard McLeod, PharmD, *University of North Carolina at Chapel Hill*
Julian Molina, MD, *Mayo Clinic*
Katie Nason, MD, *University of Pittsburgh*
Donna Niedzwiecki, PhD, *Alliance Statistical and Data Center*
James Omel, MD
Michael Redden, JD, *Duke Clinical Research Institute*
Jann Sarkaria, MD, *Mayo Clinic*
Rebekah White, MD, *Duke University Medical Center*
Dennis Wigle, MD, *Mayo Clinic*
Lee Wilke, MD, *University of Wisconsin Hospital*
Todd Zimmerman, MD, *University of Chicago*
Robin Zon, MD, *Elkhart General Hospital-CCOP*

Who Do I Contact?

Looking for specific information about Alliance operations? Use this list to find what you need within three categories: General Information, Membership and Study Information.

GENERAL INFORMATION

Conference Calls				
Bernice Williams	Executive Assistant	(773) 702-5067	secretary@calgb.org	
Meetings / Travel				
Katherine Faherty	Administrative Coordinator	(617) 732-8919	kefaherty@partners.org	
Policies				
Trinidad Ajazi	Chief Administrative Officer	(773) 702-8672	tajazi@uchicago.edu	

MEMBERSHIP

Institutional Membership Applications				
Marcia Kelly	Administrative Coordinator	(773) 834-7676	marciak@uchicago.edu	

STUDY INFORMATION

Protocol General Operations				
Michael Kelly	Director of Protocol Operations	(773) 702-8812	mkelly1@uchicago.edu	
Angie Patterson-LaBaw	Coordinator of Research Operations		patterson.angela@mayo.edu	
Jackie Lafky	Medical Writer		lafky.jacqueline@mayo.edu	
Krista Garbacz	Protocol Information Specialist	(773) 702-9269	kgabacz@uchicago.edu	
Deb Gardner	Quality Assurance, Amendments		gardner.debra@mayo.edu	
Concept Submission		alliance.concepts@calgb.org	
Publications		pubscoord@calgb.org	
Protocol Coordinators by Disease Area				
Breast				
Heather Becker	Protocol Coordinator	(773) 834-2546	hpbecker@uchicago.edu	
Cancer Control				
Tamra Losinski	Research Protocol Specialist		chomjak.tamara@mayo.edu	
Health Outcomes				
Tracee Shevlin	Research Protocol Specialist		shevlin.tracee@mayo.edu	
Prevention				
Jennifer Sickel	Research Protocol Specialist		sickel.jennifer@mayo.edu	
GI				
Shivani Shah	Protocol Coordinator	(773) 834-4518	sshah11@uchicago.edu	
GU				
John Taylor	Senior Protocol Coordinator	(773) 702-1767	jtaylor1@uchicago.edu	
Leukemia / Leukemia Correlative Science				
Michele Seiler	Senior Protocol Coordinator	(773) 834-4091	msexton@uchicago.edu	
Lymphoma / Transplant				
Morgen Alexander-Young	Protocol Coordinator	(773) 702-4236	malexanderyoung@uchicago.edu	
Neuro-Oncology				
Sanna McKinzie	Research Protocol Specialist		mckinzie.sanna@mayo.edu	
John Taylor	Senior Protocol Coordinator	(773) 702-1767	jtaylor1@uchicago.edu	
Novel Therapeutics				
Tamra Losinski	Research Protocol Specialist		chomjak.tamara@mayo.edu	
Respiratory				
Colleen Watt	Senior Protocol Coordinator	(773) 702-4670	cboyle@uchicago.edu	

For all other issues related to each legacy Group (ACOSOG, CALGB and NCCTG), the contact list remains the same. An updated list will appear in the next issue of this newsletter and on the Alliance web site.

New Alliance Appointments*

Office of the Group Chair

Patient Advocates Committee – *Chair*
Patient Communications Committee – *Chair*
Associate Liaison for Advocacy

Cynthia Chauhan
Deborah Collyar
Bettye L. Green

Experimental Therapeutics Committee – *Co-Chairs*

Charles Erlichmann, MD
Gary Schwartz, MD

American College of Surgeons Clinical Research Program

Member Services – *Chair*
Education – *Chair*
Cancer Care Standards Development – *Chair*
Research and Development – *Chair*

Mitchell Posner, MD
Henry Kuerer, MD, PhD
James Fleshman, MD
Stephen Edge, MD

**Other appointments are currently underway.*

Understanding Alliance Institutional Membership

The Alliance is ready to accept membership applications from new and existing transition members. Each of the members of the legacy Groups (NCCTG, CALGB and ACOSOG) will be required to apply to the Alliance by December 31, 2013. Alliance membership is contingent upon several requirements including: accrual, data quality and timeliness, audit performance, adherence to Alliance policies and procedures, and participation in Alliance scientific activities.

The Alliance membership will be organized in different levels representing the magnitude of accrual. **Full members** represent the institutions with the highest accruals, and the full member network is expected to credit the Alliance for at least 50 patient registrations annually to cooperative group clinical trials.

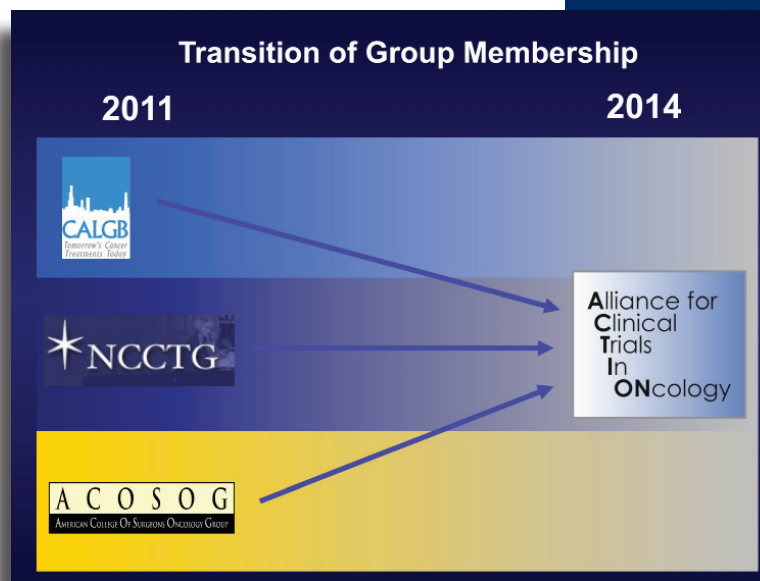
Associate member networks accrue at a lower level, crediting the Alliance for at least 30 patient registrations annually to cooperative group clinical trials. A full or associate member institution may have affiliate members or may be a stand-alone institution.

Affiliate members are institutions that are granted membership by virtue of a formal association with a full or associate member. These institutions will credit the Alliance for at least five patient registrations per year.

Each member institution will have a principal investigator (PI), who is primarily responsible for any and all activities related to the Alliance at the institution/network. All PIs are required to follow the Alliance Policies and Procedures, including maintenance of current roster data and other membership information.

Each full and associate member shall also have a co-principal investigator, who will assume responsibility in place of the principal investigator, if for any reason the PI is unable to perform duties required for Alliance institutional membership.

Application materials and frequently asked questions (FAQs) for the Alliance can be found on the Alliance web site at www.alliance-website.org, and questions can be directed to Marcia Kelly (marciak@uchicago.edu, 773-834-7676).



ALLIANCE NEWS

ALLIANCE NEWS is published by the Alliance for Clinical Trials in Oncology bi-monthly and distributed to the Group's active membership through the Alliance website (www.alliance-website.org) and by broadcast e-mail. ALLIANCE NEWS reserves the right to make corrections, changes and deletions in submitted copy in conformity with the newsletter's editorial policies.

Forward all correspondence to Jamilah Owens, Alliance Communications Specialist, at jowens@uchicago.edu.

2011-2012 Alliance Meeting Dates

2011 Fall Group Meeting

November 17-19, 2011

InterContinental Chicago O'Hare
Rosemont, IL

2012 Spring Committee Meetings*

March 15-17, 2012

InterContinental Chicago O'Hare
Rosemont, IL

2012 Summer Group Meeting

June 28-30, 2012

InterContinental Chicago O'Hare
Rosemont, IL

2012 Fall Committee Meetings*

November 15-17, 2012

InterContinental Chicago O'Hare
Rosemont, IL

For questions regarding Alliance meetings and travel information, please contact Katherine Faherty, Alliance Administrative and Meetings Coordinator, at 617-525-3022 or kefaherty@partners.org.

**Closed meetings open to members of committees or invited guests.*

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Alliance for Clinical Trials in Oncology

Office of the Group Chair

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