Pathways Study

Publications, Presentations, and Ancillary Studies Policy

Last Updated: September 19, 2011

Overview

The Pathways Study and it related grants are building a resource that enables investigation of the association of numerous factors with breast cancer patterns of care, prognosis and other outcomes. Because the range of topics and interested investigators may be substantial, it is helpful to have policies on publications, presentations, and ancillary studies that follow several general guidelines:

a. Assurance that this resource is being shepherded appropriately, so that limited resources are not squandered (e.g., see associated Biospecimen Access Policy), nor are resources not used to disseminate knowledge (e.g. the substantial questionnaire and clinical data that are being collected and assembled);
b. Assurance that investigators interested in a given topic have the opportunity to participate, while balancing that with the need to limit active input into a given manuscript;
c. Assurance that junior investigators and interested staff have adequate opportunity to contribute to and take the lead on publications and presentations;
d. Monitoring to avoid overlap of topics and equitable distribution of authorship opportunities;
e. Tracking to ensure that commitments that have been made are followed in a reasonably timely fashion.

I. Publications and Presentations from Pathways Study:

a. Publications Committee:
   i. Membership: A Pathways Publications Committee of six individuals consisting of the *1)* Principal Investigator, *2)* all Subcontract Principal Investigators, *3)* one other DOR Investigator, and *4)* one person from among all other related grant investigators, ancillary study investigators, and consultants, or their designees, will constitute the Publications Committee. The Pathways Project Manager will serve as an *ex officio,* non-voting member of this Committee.
   ii. Ad hoc members: For any given topic proposed for analysis and publication, if expertise in the topic under consideration is not represented on the Publications Committee, at least one other person from among Pathways investigators with substantive knowledge of the topic will also be an ad hoc member of the Committee. If the topic involves areas under investigation in one or more Ancillary Studies, the Ancillary Study Principal Investigator(s) will also be an ad hoc member of the Publications Committee.
   iii. Logistics: Terms of service will be two years for the two members selected from among DOR Investigators and other Investigators, renewable indefinitely. These

Publications Committee members will be selected from among the relevant pool of individuals according to methods of their own choosing. The Chair of the Publications Committee will be selected from among the Publications Committee at their discretion, using methods of selection of their own choosing.

iv. Documentation: Paper topic outlines, approvals, and other related materials will be kept by the Pathways Project Manager or that person's designee (in consultation with the Pathways Principal Investigator).

b. Timing of Paper Topic Proposal: In general, paper topics should be proposed when data are available to address that topic or are anticipated to be available within 6 months. Exceptions include if there exists the need to collect additional data to address the topic of the proposed paper, such as when biospecimens need to be analyzed, or when additional data may need to be collected for the specific topic. In such cases and if appropriate, procedures for approval of Ancillary Studies or Biospecimen Use should also be followed.

c. Proposing a Paper Topic: When an investigator/author is ready to begin analyses on his/her topic, he/she should formally draw up an outline of the paper. This outline should contain:

i. Question(s) to be addressed
ii. Significance of research question
iii. Hypothesis testing (if necessary)
iv. Analytic aims
v. Variables to be used
vi. Statistical approach
vii. Tentative list of authors
viii. Proposed timeline

Because of the collaborative nature of the Pathways Study, it is recommended that all study investigators and collaborators be offered the opportunity to participate in analysis, data interpretation, and communication of results if they have something to contribute to the process. This may be done by the proposing investigator/author prior to submission of the topic. If possible, paper topic outlines should be reviewed by all proposed co-authors prior to submission.

d. Submission of Topic Outline: The paper topic outline will be submitted to the Publications Committee (through the Pathways Project Manager) for review and approval.

e. Review of Topic Outline: In order to ensure that all interested investigators and collaborators are provided the opportunity to participate, paper topic outlines will be distributed to all Pathways investigators and collaborators for their information. If any individual not already listed on the tentative list of authors expresses interest in the topic, that interest should be expressed to the originating investigator and the Publications

Committee. Please review the list of investigators on Attachment 1 to ensure that all potentially interested investigators are included.

f. Analysis/Publication Approval: While others have had an opportunity to provide input into the topic, the Publications Committee will decide on approval, modification, or disapproval of the proposed topic. In general, this review process should take no longer than two weeks, given the vagaries of Committee members' schedules.
   i. If the topic is approved, the investigator/author can proceed with the proposed analysis.
   ii. If modifications to the topic are suggested, the investigator/author can elect to modify the topic and resubmit a modified topic outline to the publications committee within two weeks.
   iii. If the topic is disapproved, the reasons for disapproval will be provided, along with alternative suggestions if appropriate.

g. Authorship of Manuscripts: Authorship on all key collaborative papers and presentations will include the Pathways Principal Investigator and subcontract Principal Investigators unless they decline authorship. The first author will be the individual who played a major role in manuscript preparation and usually also oversaw data analysis. The last author will represent the senior author on the paper, which will usually be either the Principal Investigator of the Pathways study or ancillary studies or lead investigator on the analysis or topic area.

   If the topic involves Ancillary Study data, authorship will include the Principal Investigator(s) of the Ancillary Study unless they decline. Authorship on publications will require contribution to the manuscript according to generally accepted guidelines for authorship on peer-reviewed articles (such as involvement in study design, conduct, analysis, interpretation, or manuscript writing).

h. Acknowledgment of Pathways Funding Support: All manuscripts, abstracts, and presentations must acknowledge support of the core Pathways Study grants (R01 CA105274, U01 CA195565). If Ancillary Study data or activities are involved, those funding sources should also be acknowledged. Refer to Attachment 2 for a list of ancillary studies and associated grant numbers. We suggest citing all grants that funded data collection or relevant activities when appropriate.

i. Reporting Your Work to the Pathways Study Master Bibliography: All manuscripts which have been submitted, are in press, or published should be reported to the Publications Committee in order to be included in the study's master bibliography. This policy also applies to conference abstracts and presentations. Updates on any changes to journal submission should also be reported to the Publications Committee.

j. Tracking of Paper Topics: Progress on paper topics will be tracked by noting the date of topic submission, date of approval, date of distribution of initial draft for comment, and dates of submission and acceptance for publication. All submitted and published (PDF if

available) manuscripts should be sent to the Publications Committee for the study archives.

Competed manuscripts should be submitted to the publication committee prior to submission to ensure that variables are used in a standard manner and that the study is being described appropriately. The publication committee should review papers in 2 weeks or less and provide written feedback about concerns about analysis or conclusions.

k. Abstracts for Presentation: In general, approval of topics for presentation will follow the same procedures as outlined above. Indeed, if a topic is approved for a manuscript, it is generally encouraged that findings be submitted for presentation at an appropriate scientific meeting, if timing is appropriate.

It is recognized that on occasion, submission of abstracts may be done at the last moment, under a rapidly approaching deadline. In these instances, prior approval following the above procedures is not necessary. However, the Publications Committee should be notified about the proposed presentation, and a copy of the abstract sent to the Publications Committee. The authors are encouraged to disseminate the abstract idea to other investigators to ensure that those who are interested are aware of the abstract and have the opportunity to provide input. Note that submission of an abstract and presentation under these circumstances does not automatically give the author(s) approval to move forward on that topic for preparation of a manuscript, unless the topic has been approved following the above procedures.

l. List of Potential Topics/Hypotheses: The following folder lists the topics/hypotheses individuals would like to pursue in the Pathways Study and lists interested investigators and possible lead investigators/authors on each topic:

J:\BREAST CANCER SURVIVORSHIP\Publications\Pathways Publications\Paper Topics

m. Key Investigators and Publications Committee Members: A list of investigators who are considered to be “key” is provided in Attachment 1 of this policy.

II. Ancillary Studies to Pathways Study

a. Definition: Ancillary Studies may or may not be funded by an external funding agency. However, ancillary studies invariably involve additional data collection, whether that involves analysis of biospecimens, collection of pilot or validation data, or adding data elements to the Pathways Study. Current Pathways ancillary studies are listed at the end of this policy.

b. Ancillary Study Research Proposal: An investigator or group of investigators who wishes/wish to undertake an ancillary study must prepare a formal research proposal describing the proposed study. This proposal should contain:

   i. Initiating investigators; planned start date; funding plans and estimated costs
   ii. Brief background and rationale
   iii. Study questions or hypotheses
   iv. Study timeline
   v. Sample size, justification
   vi. Methods, data to be collected
   vii. Biospecimens required (if any) and proposed assays
   viii. Data needed from main study for analysis of ancillary study data

c. Ancillary Study Review:

   i. An Ancillary Studies Committee will review the proposed research project. This Committee will consist of the same individuals as the Publications Committee; the review of ancillary studies can be viewed as a related, but separate task from review of paper and presentation topics, and will follow similar procedures, including inclusion of ad hoc reviewers when appropriate.

   ii. After review of the proposal, the Committee may recommend approval, conditional approval, or disapproval. These recommendations will be sent to the initiating investigator(s). If a proposal is recommended for approval or conditional approval, the investigators are encouraged to search out other interested co-investigators among the extended Pathways research team.

   iii. After review of the recommendations, the investigator(s) may amplify, clarify, or withdraw his/her/their request. A proposal which has received conditional approval must be resubmitted to the Committee for final consideration. After final review of the proposal, the investigators will prepare a statement of its consensus, including any reservations or objections, and will send this statement to the initiating investigator(s).

   iv. Criteria for Approval of Ancillary Studies: Ancillary studies will be approved considering not only the scientific merit and potential contribution to the clinical or public health knowledge, but also its potential impact on participant burden,

loss to follow-up, feasibility within the Pathways Study context, use of finite resources, overlap with ongoing Pathways projects, and likelihood of funding.

v. Approval Suspension: The Ancillary Studies Review Committee can vote to temporarily or permanently suspend an Ancillary Study if, following initial approval, there is evidence that changes the conditions under which the original approval was granted.

d. Ancillary Study Progress Reports:

The reviewing investigators will monitor the development of the ancillary studies, determine whether they have received funding, record their initiation and projected project completion dates, and monitor their progress. An annual written progress report on ancillary studies will be requested from the principal or lead investigator(s) for the ancillary study. A copy of annual reports that are filed to funding agencies will suffice for this requirement, if applicable.

e. Ancillary Study Publications and Presentations:

All presentations and publications from the ancillary studies that use Pathways data are subject to review and approval by the Publications and Presentations Committee in accordance with requirements outlined in the Publications Policy above. In such cases, the Publications and Presentations Committee will include the Principal or Lead Investigator for the ancillary study and other individuals who that person deems necessary. In addition, topic proposals may not be widely distributed to Pathways investigators, depending on the nature of inclusion of Pathways data and the extent of inclusion of non-Pathways/KPNC data.

f. List of Ancillary Studies:

Ongoing, funded, proposed, and completed ancillary studies are listed in Attachment 2.

ATTACHMENT 1.

Lists of key individuals who serve on the Publications Committee, or who should be considered for co-authorship in selected domains (list current as of May 22, 2017).

Pathways Study Role / Topic Areas	**Investigator Name**
Administrative Roles and Key Authors	
PI	Larry Kushi (DOR)
Co-investigator	Marilyn Kwan (DOR)
Subcontract PI: Roswell Park Cancer Institute	Christine Ambrosone (Roswell)
Subcontract PI: UCSF	Marion Lee and John Wiencke (UCSF)
Subcontract PI (1st funding period), Consultant (2nd funding period): Zero Breast Cancer	Janice Barlow (Zero Breast Cancer)
Subcontract PI: Cancer Prevention Institute of California (2nd funding period)	Scarlett Lin Gomez (CPIC)
Pathways Project Manager	Janise Roh (DOR)
Ancillary Studies - past and current	
Antioxidants and Adjuvant Therapy PI (funded by NCI)	Heather Greenlee (Columbia)
Adjuvant Breast Cancer Therapies PI (funded by ACS)	Dawn Hershman (Columbia)
Food Record Documentation (funded by FHCRC and NCI)	Alan Kristal (FHCRC)
Physiology of Aging PI (funded by NCI)	Jeanne Mandelblatt (Georgetown)
Racial Disparities PI (funded by DOD)	Al Neugut (Columbia), Dawn Hershman (Columbia)
Genetics of Tamoxifen Response PI (funded by CBCRP)	Elad Ziv (UCSF)
Lymphedema PI (past funded by ACS)	Marilyn Kwan (DOR)
Topic Areas (investigators not otherwise listed above)	
Food and Nutrition, Energy Balance	Bette Caan (DOR)
Physical Activity	Barbara Sternfeld (DOR)
Complementary and Alternative Therapies	Harley Goldberg (KPNC)
Psychosocial Factors	Carol Somkin (DOR), Anita Stewart (UCSF)
Tumor DNA Methylation	John Wiencke (UCSF), Shichun Zheng (UCSF), Brock Christensen (Brown)
Pharmaceuticals	Laurie Habel (DOR)
Interpersonal Process of Care (IPC)	Anita Stewart (UCSF)
Taxanes	Dawn Hershman

ATTACHMENT 2.

List of ancillary studies - past, current and proposed.

Principal Investigator(s)	**Institution**	**Topic**	**Funding Agency**	**Agency Grant No.**	**Pathways Study Contact**
Completed					
Marilyn Kwan	Kaiser Permanente Northern California	Predictors and sequelae of lymphedema	American Cancer Society	RSG-06-209-01-LR	Marilyn Kwan
Alan Kristal	Fred Hutchinson Cancer Research Center	Precision of food records with or without follow-up documentation	FHCRC internal funding		Marilyn Kwan
Ongoing or Funded					
Al Neugut, Dawn Hershman	Columbia University	Racial disparities in chemotherapy and outcomes	Department of Defense Breast Cancer Research Program	BC043120	Janise Roh
Dawn Hershman	Columbia University	Adjuvant breast cancer therapies: Race, Variations in Care and Survival	American Cancer Society	RSGT-08-009-01-CPHPS	Janise Roh
Jeanne Mandelblatt	Georgetown University	Physiologic age and chemotherapy	National Cancer Institute	R01 CA124924	Janise Roh
Elad Ziv	UCSF	Genetics of tamoxifen response	California Breast Cancer Research Program	14OB-0166	Janise Roh
Bette Caan	Kaiser Permanente Northern California	Molecular profiles and lifestyle factors in breast cancer prognosis	National Cancer Institute	R01 CA129059	Marilyn Kwan
Heather Greenlee	Columbia University	Antioxidant use and adjuvant therapy	National Cancer Institute	K23 CA141052	Janise Roh
Larry Kushi	Kaiser Permanente Northern California	Building CER capacity: Aligning CRN, CMS, and state resources to map cancer care	National Cancer Institute	RC2 CA148185 UC2 CA148185	Janise Roh

Principal Investigator(s)	Institution	Topic	Funding Agency	Agency Grant No.	Pathways Study Contact
Li Tang	Roswell Park Cancer Institute	Nutrigenetics of cruciferous vegetable intake and breast cancer prognosis	National Cancer Institute	K07 CA148888	Larry Kushi
Marilyn Kwan, Song Yao	Kaiser Permanente Northern California	Lifestyle and molecular factors of bone health in breast cancer survivors	National Cancer Institute	R01 CA166701	Marilyn Kwan
Laurel Habel	Kaiser Permanente Northern California	Mammographic density & prognosis among breast cancer intrinsic subtypes □	National Cancer Institute	R01 CA168893	Larry Kushi
Larry Kushi	Kaiser Permanente Northern California	Genome-wide association studies of breast cancer prognosis & treatment outcomes	NHGRI / NCI	X01 HG008335	Larry Kushi
Susan Neuhausen, Elad Ziv	City of Hope	Germline and tumor genomic analyses of breast cancer in Latinas	National Cancer Institute	R01 CA184585	Larry Kushi
Candyce Kroenke	Kaiser Permanente Northern California	Social networks, breast cancer treatment, and survival	National Cancer Institute	K07 CA187403	Candyce Kroenke
Proposed					
Elad Ziv	UCSF	Analysis of breast cancer risk loci in Latinas: combining functional and population genetic analyses	National Cancer Institute	R01 CA208102	Larry Kushi
Marilyn Kwan, Heather Greenlee	Kaiser Permanente Northern California		NCI / NHLBI		Marilyn Kwan

Principal Investigator(s)	Institution	Topic	Funding Agency	Agency Grant No.	Pathways Study Contact
Song Yao, Larry Kushi, Scarlett Lin Gomez	Roswell Park Cancer Institute	Neighborhood Social Context, DNA Methylome, and Disparities in Breast Cancer Survival in the Prospective Pathways Study	NCI, NIMHD		Larry Kushi