

## Greater Plains Collaborative (GPC) Breast Cancer Study Publication Policies

### Goals of Publication Policies

Publication policies are intended to promote high standards and effectiveness for GPC publications without creating unnecessary barriers to investigators' scholarship and productivity. Policies are intended to:

1. Assure that manuscripts resulting from the Phase 1 *GPC Share Thoughts on Breast Cancer Study* are published in a timely manner;
2. Maintain uniform, high standards for GPC publications and assure that the underlying analyses are consistent with each other;
3. Track the progress of articles and presentations and disseminate this information to GPC members;
4. Prevent duplication of effort in analyses and the preparation of manuscripts;
5. Assure that authorship, with its associated responsibilities and credit, is distributed equitably among members of the GPC Breast Cancer Group;
6. Prevent disputes over the right to pursue research questions and over authorship, and facilitate the resolution of disputes if they arise.
7. Anticipate future collaborative studies of the GPC-BCG as well as products from the Phase 1 study

### Terminology

- **Greater Plains Collaborative** or **GPC** is used when referring to all member institutions collectively and generally, without regard to the breast cancer topic area specifically
- **GPC Breast Cancer Group** or **GPC-BCG** refers to the interest group that leads the GPC research agenda, inclusive of researchers from any GPC member institution
- **GPC Share Thoughts on Care Study** refers to all data collection, linkage and analysis activities within the 5 specific aims named in the Phase 1 study protocol. Some restrictions may apply to publications using the Phase 1 data.
- **GPC Breast Cancer Study** data refers to research studies conducted by the GPC-BCG in Phase 1, Phase 2, or beyond.
- **GPC-BCG Publications Committee** or **Publications Committee** refers to the Committee charged with oversight of the publication policies for the GPC-BCG. One representative from each GPC institution
- **GPC Breast Cancer Cohort Lead** for the period of the Phase 2 award is Elizabeth Chrischilles
- **Publications Leadership Committee**, a few members of the Publications Committee who, will take primary responsibility for the day-to-day work of the Committee and provide continuity

## **The Publications Committee**

Oversight of GPC-BCG publications is mainly carried out by a Publications Committee.

### ***Membership***

The GPC-BCG Publications Committee will include:

- One representative from each GPC institution as designated by the institution principal investigator
- The GPC Breast Cancer Cohort Lead or designee
- The GPC-BCG statistician or designee
- A patient representative as designated by the GPC patient engagement lead

A Publications Leadership Committee consisting of a Chair and a leadership group of up to three members, all members of the Publications Committee, will take primary responsibility for the day-to-day work of the Committee and provide continuity. This arrangement will allow publications of GPC Breast Cancer Study results to receive the individual, concentrated, ongoing attention they require while embedding this activity in the larger Publications Committee.

### ***Responsibilities***

The Publications Committee is responsible for providing oversight over all intellectual products of the GPC Breast Cancer Study throughout the research process, from requests for preliminary analyses, through proposals for analyses leading to manuscripts, abstracts of results for presentations at scientific meetings, manuscripts to be submitted to journals, and any other public exposures of GPC Breast Cancer Study results. The policies apply whether the study is an analysis of GPC-wide data, data collected as part of the GPC Breast Cancer Study work but only at the local level, or studies using GPC Breast Cancer Study data in which non-members initiate or participate.

The Publications Committee will do most of its work by emails and meet by conference call as often as necessary, according to the workload, with prior notification of all members.

### **Proposals**

Proposals for projects may be initiated by members of the GPC-BCG or members in conjunction with non-members. Proposals from non-members should include plans for how a GPC-BCG member will be substantially involved in the work and responsible for assuring that analyses and resulting manuscripts follow all the usual procedures and meet standards for proposals initiated by GPC-BCG members.

### ***Format***

Proposals should be sent to the Publications Committee in the template posted on the GPC Breast Cancer Study website. They should include the following information:

1. Lead investigator and contact information
2. Project title

3. Proposed collaborators (members of the writing team)
4. Scientific and policy background and rationale
5. Research question (and/or hypotheses when appropriate)
6. A brief description of the variables needed and analysis plan
7. Proposed time line
8. Qualifications of investigators to address the particular research question
9. Possibilities for overlap with other GPC Breast Cancer Study analyses and plans for resolution
10. Key words

If a single proposal for data analyses evolves into multiple related manuscript proposals, a separate proposal should be prepared for each, reviewed, and posted on the GPC Breast Cancer Study website.

### ***Writing Teams***

A writing team will be formed for each proposal, to plan data analyses and prepare the resulting manuscript. A team leader will be responsible for submitting requests for use of GPC Breast Cancer Study data to the Publications Committee and for leading the project to completion. The writing team leader will assemble a core writing team and name them in the proposal.

Additional writing team members will be identified as follows: GPC-BCG members will receive a summary of all approved proposals after each GPC-BCG conference call and invited to contact the lead author about joining the writing team if they believe they can contribute to the work because of their expertise, experience, and engagement in similar research questions. The writing team leader will decide on authorship, with the advice and consent of the Publications Committee. Investigators who believe they can contribute to the work, because of expertise, experience, and interest, will contact the leader of the writing team, who will decide whether to add that investigator to the writing team. The Publications Leadership Committee will participate in decisions about writing team membership if needed. All writing teams should include a local statistician affiliated with the GPC.

### ***Review Process and Decisions***

Proposals for data analyses leading to manuscripts will be reviewed by the Publications Committee. Each will be sent for review to all members of the Publications Committee. Results will be summarized by the Chair, in communication with other members of the Leadership Committee. Review should ordinarily be accomplished in about 2 weeks. Approval will be by the Leadership Committee unless it chooses to involve the GPC-BCG in the decision.

Some proposals ask research questions that are related to others already approved. Primary responsibility for avoiding overlap lies with the writing team leaders themselves as they prepare their proposals. However, the Publications Committee, through its Chair, will make every effort to identify related work within the GPC-BCG. If there appears to be related plans, the Chair will ask that leaders of new proposals discuss their work with leaders of the other proposals and provide a summary of how the overlap will be reconciled as a condition for approval.

### ***Monitoring Progress***

The Publications Committee and the writing team leader will agree on a reasonable timeline for each research paper. If in the opinion of the Publications Committee a writing team is not functioning well or there is an unjustifiable delay in writing the manuscript it has taken responsibility for, the Committee

can change either the leader or the entire membership of the writing team, to expedite the writing of that particular paper.

## **Manuscripts**

### ***Review Process***

All manuscripts reporting results from GPC Breast Cancer Study data must be reviewed and approved by the Publications Committee before being submitted to a scientific journal. Manuscripts will be reviewed by all members of the Publications Committee. Additional reviewers, chosen from the GPC-BCG membership, may be added if a manuscript involves expertise not represented on the Publications Committee. Uncomplicated reviews will generally be accomplished in about two weeks.

### ***Decisions***

The Chair of the Publications Committee, with the advice and consent of the Leadership Committee, will summarize the decision at three levels: approval without need for further review, conditional approval depending on the results of additional review by the Publications Committee before submitting to a journal, or disapproval. The Chair will communicate the decision, along with suggestions for improvement, to the lead author. The Publications Committee will summarize its decisions for GPC-BCG members at each of the Group's regular conference calls. The Leadership Group of the Publications Committee will seek the advice of the full GPC-BCG as needed. Authors who disagree with decisions of the Publications Committee can appeal these decisions to the GPC-BCG.

### ***Authorship***

The writing groups should discuss order of authorship when they begin working together and should revisit this issue throughout the process of manuscript preparation, since roles do change and contributions may in practice become different from what was expected at the beginning of the project. Although relative contribution to the work is a major criterion for order of authorship, writing groups are free to assign order in other ways, such as alphabetical or random order, and to request that journals publish this information with the manuscript. All investigators who have made substantial intellectual contributions to a manuscript, whether or not they are authors, should agree among themselves on the types of contributions each made, and the lead author should record this agreement and submit a summary of it to the Publications Committee and to the journal with the manuscript.<sup>1</sup>

The Publication Committee's criteria for authorship will be guided by those of the International Committee of Medical Journal Editors (ICMJE, the "Vancouver Group"<sup>2</sup>):

- Authorship credit should be based on 1) substantial contributions to the conception, design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3 ..."
- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

These criteria are similar to those of other major organizations concerned with authorship, especially those written recently.

### ***Recognizing GPC-BCG Members in Publications***

Each GPC Breast Cancer Study manuscript will be written by a limited set of members on behalf of many others who have participated in research design, instrument development, and data collection. In general, the GPC-BCG seeks to limit the number of authors to about 8, with the understanding that more authors are justified for some manuscripts.

Prominence of recognition of Group members, short of authorship, will be in relation to the importance of the manuscript to the GPC-BCG as a whole and will be decided on a case by case basis, guided by the following general principles:

1. Contributions of the GPC as a whole will be recognized on high-priority manuscripts by including it in the title or adding “for the Greater Plains Collaborative” to the end of the list of named authors.
2. For manuscripts considered central to the GPC-BCG mission, an investigator from each GPC site will have an opportunity to be an author, over and above writing team members (see “High-Priority Manuscripts” below)
3. For most other manuscripts, other members of the GPC-BCG will be recognized as a group in the Acknowledgement section of the manuscript, without mentioning individual names (to reduce length and to avoid arduous collection of signatures). A complete, user friendly list of GPC-BCG members and institutions should be made available on the web and referred to in the manuscript when appropriate.
4. Some GPC-BCG manuscripts, such as those based on ancillary or methodologic studies, may not have involved enough GPC members to warrant recognition of the GPC-BCG as a whole.

None of these options implies that GPC-BCG members other than those named in the manuscript are authors. This approach to recognizing GPC-BCG members’ contributions is over and above recognition of funding, which should be included in every manuscript.

**High Priority Manuscripts.** The Publications Committee will designate some manuscripts as “High Priority,” guided by existing documents (the grant proposal, the study protocol, and minutes and slide presentations from study development webinars). For High Priority Manuscripts using the *Share Thoughts on Care Study* data, each of the 8 GPC institutions that collaborated on the *Share Thoughts on Care Study* will have the opportunity for one named author, in addition to other authors who were on the writing team. For these manuscripts, the number of authors may exceed the usual maximum of eight to accommodate both primary authors and site representatives. As with other GPC-BCG manuscripts, all authors must meet criteria for authorship.

### **Abstracts**

Abstracts of GPC-BCG work that will be submitted to scientific meetings and perhaps published in their proceedings will be reviewed by the leadership group of the Publications Committee before submission. As a practical matter, such abstracts are often prepared just prior to the deadline and a two-week review will not be required, as long as there is sufficient time to make an informed decision.

### **Ancillary Studies**

An ancillary study is one that uses GPC data but is supported by funds other than those awarded for the GPC Breast Cancer Study. Most ancillary studies also involve acquisition of additional data that are merged with core GPC data. Ancillary studies are an opportunity to expand the use of GPC data to answer important questions that could not otherwise be addressed with the core resources and data. A GPC investigator must be a principal investigator or co-investigator on all Ancillary Studies.

Before investigators enter into an agreement with a funding agency to do an ancillary study, a proposal must be reviewed by GPC and approved in writing. Proposals for Ancillary Studies involving breast cancer research are submitted to the GPC-BCG Publications Committee in the same format as other proposals but include additional information on:

- where, when, how, and on whom additional data will be collected
- funding source and assurance that additional support will cover the additional effort and time necessary to complete the study
- a statement from participating GPC institutions that they agree to participate
- plans for additional IRB approvals

Procedures for Ancillary Studies are otherwise the same as for other GPC Breast Cancer Study analyses. Proposals will be approved by the usual process but, in addition to the usual criteria for approval, the Publications Committee will consider whether:

- the objectives of the work are close to, and do not interfere with, those of GPC-BCG
- the proposed study will compromise the success of the main GPC Breast Cancer Study
- additional data collections would result in an inordinate burden on GPC Breast Cancer Study participants.
- the additional funding covers the additional work necessary to complete the study

If the structure or concept of an Ancillary Study changes after approval, the Publications Committee will need to approve the alterations.

All products of the proposed analysis, including meeting abstracts and manuscripts for publication, must be approved by the Publications Committee before being submitted to a journal.

### **Communications and Record Keeping**

The Chair of the Publications Committee will provide a summary of all Committee decisions to the GPC-BCG, where they will part of the records of those calls.

The GPC will support monitoring of publications activities through development and maintenance of an appropriate database with standardized and customized reporting capabilities. This database will be posted on or linked to the GPC website where it will be available to all members of the GPC.

The leader of the writing team is responsible for notifying the Publications Committee of journal, dates of submission, reviews, resubmission, and acceptance or rejection as well as copies of reviews and other correspondence surrounding journal review. Supported by the GPC, the Publications Committee will keep written records of its transactions, including minutes of regular meetings. It will request from the

GPC-BCG summary reports of all publication activity, with the expectation that each GPC-BCG representative will communicate this information to members of their research teams. Authors will deposit the analytical files and statistical models associated with publications with the GPC-BCG Coordinating Center.

### **General Publication Policies**

#### ***Confidentiality.***

Identifiers of individual patients, health care providers, practice organizations, health care plans, or insurers will not be included in a data set or in publications without prior written consent.

#### ***Conflict of Interest***

If GPC investigators have financial interests related to the research projects they participate in, they must declare those interests when asked to review GPC manuscripts and follow the policies regarding conflict of interest of the journals to which they submit their research.

#### ***Acknowledging Funding Source***

All articles resulting from GPC should recognize all financial support for the project including PCORI, the National Cancer Institute, or others, according to the data and resources used. A current version of this information will be posted on the GPC website. Should there be a necessity for “signoff” of manuscripts by agencies in which some authors reside, such as the National Cancer Institute, it will be the responsibility of the respective authors to be certain that relevant signoff has been obtained before manuscripts are submitted for publication.

#### ***PCORI Review***

Under the terms of the PCORI contract, PCORI must be provided with the opportunity to review and comment on the draft article or manuscript prior to its submission for publication or distribution. PCORI will provide comments not later than fourteen (14) days after the provision of the draft to PCORI.

#### ***PCORI Notification of Accepted Presentations and Publications***

Under the terms of the PCORI contract, the PCORI Contract manager must be provided via email all accepted presentations and full-length peer-reviewed publications arising from the project prior to the publication date and within thirty (30) days of acceptance.

#### ***Acknowledging the GPC***

It is expected that GPC will be mentioned in the title of all multi-site articles based on GPC data. This helps in indexing and retrieval and in gaining recognition for the GPC. All manuscripts based on GPC-wide data should also include a footnote or appendix listing the GPC Breast Cancer Study institutions with principal investigators.

### **References**

1. Rennie D, Yank V, Emanuel L. When authorship fails. A proposal to make contributors accountable. *JAMA* 1997;278:579-85.
2. <http://www.icmje.org> (Accessed January 10, 2006)