



Comprehensive Assessment of Long-Term Effects of Reducing Intake of Energy

Publication Policy

1. INTRODUCTION

The Comprehensive Assessment of Long-Term Effects of Reducing Intake of Energy (CALERIE) is a collection of studies designed to evaluate the effects of calorie-restricted diets on human physiology, metabolism, body composition and adverse events. These studies are sponsored by the National Institute on Aging (NIA). Grants were originally awarded to the Pennington Biomedical Research Institute, Tufts University and Washington University. Each site was charged with developing and evaluating its own intervention approach. Sites are collecting data specific to their own needs as mandated by their protocols. Nevertheless, CALERIE investigators recognized that there is much to be gained from standardizing procedures as much as possible, and a grant was awarded to the Duke Clinical Research Institute (DCRI) to serve as the CALERIE Coordinating Center (CC). Common data elements may be incorporated into a collaborative database maintained CC to enable analyses pooled across the three studies.

The results of these studies will be disseminated to the greater scientific community through presentations, abstracts and manuscripts. Non-scientific presentations and documents, e.g., course notes, departmental seminars, press-releases, interviews with the lay media, articles in magazines and newspapers, and so on are also possible. As a cooperative agreement in which they share common goals, the investigators recognize that these activities benefit from broad oversight.

A collaborative project also involves intellectual contributions from the entire cadre of investigators and staff. In an academic environment, authorship has important professional implications, and authorship on publications arising from this effort should reflect these contributions. It is important to give credit where credit is due; it is no less important to acknowledge the contributions of all staff members to the enterprise.

The purpose of this document, therefore, is to outline policies concerning the publication process. Authorship issues are discussed; a review process for abstracts and manuscripts is outlined; and, access to the collaborative database is described.

2. COMPOSITION OF THE PUBLICATIONS SUBCOMMITTEE

The Publications subcommittee (PubSc) is composed of one member from each of the sites, one from the Coordinating Center, and one from NIA. Members are nominated by their Principal Investigators (Project Officer, in the case of the NIA) and approved by the Steering Committee. The Chairman is appointed by the Steering Committee. Any change in membership is approved by the Steering Committee.

3. SCOPE AND DEFINITIONS

3.1 Types of Publications and Scope of Activities

This policy is directed primarily at two types of writing, namely, abstracts and presentations prepared for scientific meetings and conferences, and manuscripts submitted for journal publication (peer-reviewed or otherwise), book chapters, etc. In general, different procedures are prescribed for these two types of writing.

The scope of activities covered under this policy includes writing intended for a "wide" scientific audience. Presentations and seminars intended for a strictly local audience, e.g., departmental seminars, university classes, and "grand rounds" restricted to the author's home institution, are not covered by this policy. There is a considerable gray area in between, however. The local chapter of a national scientific organization is generally considered a "wide" audience because the information could be disseminated by the national parent organization.

3.2 Site-Specific vs. Collaborative Publications

Data are considered “site-specific” if they pertain to participants at only one of the clinical sites, e.g., data from the PBRC participants. Data are considered “collaborative” if they pertain to participants at two or more of the sites, and the intention is to summarize information across the two or more sites. Collaborative data may or may not be forwarded to the CC for statistical analysis and may or may not be merged into a single pooled dataset. Analyses based on site-specific data are considered “site-specific analyses.” Analyses based on collaborative data, irrespective of whether they are entered into a collaborative database at the CC, are considered “collaborative analyses.” Scientific writing based on a site-specific analysis is called a “site-specific publication,” while that based on a collaborative analysis is called a “collaborative publication.”

4. RESPONSIBILITIES OF THE PUBLICATIONS COMMITTEE

The Publications Subcommittee (PubSc) provides broad oversight to all publication activities. In general, it has the following responsibilities:

- Promote the scientific integrity of all collaborative publications.
- Promote consistency across all collaborative publications.
- Make recommendations to the Steering Committee on collaborative publications before they are submitted for publication.
- Resolve conflicts related to any type of publication.
- Draft new policies for approval by the Steering Committee as the need arises.

The PubSc may also be requested to review site-specific abstracts and publications in order to evaluate the consistency and integrity this type of writing. However, these activities are beyond its current mandate and would be done on a voluntary basis by the individual sites.

The PubSc is not specifically responsible for recommending publications to be written and identifying venues for presenting results. This comes under the purview of the Statistical Analysis subcommittee. However, the PubSc may volunteer recommendations to the Steering Committee if it is in the greater interest of CALERIE. It can also help prioritizing collaborative analyses to provide guidance to the Steering Committee.

5. RESPONSIBILITIES OF THE COORDINATING CENTER

In general, the Coordinating Center has the following responsibilities:

- Catalog all collaborative and site-specific abstracts and publications.
- Provide periodic reports to the Steering Committee on collaborative and site-specific publications in progress.
- Maintain the reprint file of all collaborative and site-specific publications.
- Distribute all collaborative abstracts and publications to internal and external groups.
- Archive all collaborative and site-specific abstracts and publications at the end of the study.
- Manage the administrative aspects of the internal review process.
- Provide biostatistical and data management advice.
- Ensure the accuracy of results reported in all collaborative publications.

To fulfill these requirements, the CC will periodically canvass CALERIE investigators requesting the current status of all collaborative and site-specific abstracts and publications prepared under these research grants.

6. AUTHORSHIP AND ATTRIBUTION

6.1 Writing Groups and “Primary Authors”

Any publication, site-specific or collaborative, is typically a collaboration of a number of CALERIE members, either at the same site or across two or more sites. This collection of CALERIE authors is called a “Writing Group.” Writing groups are expected to form spontaneously as the study unfolds and opportu-

nities to publish are revealed. Each Writing Group has an individual who takes scientific and administrative responsibility for the manuscript. This individual is called the “Primary Author.”

It will frequently occur that resources at the Coordinating Center are required for collaborative and even site-specific publications. This may consist of data held in the collaborative database as well as biostatistical and data management expertise. This implies that a CALERIE member at the Coordinating Center would be included as part of the Writing Group and serve as liaison to the Coordinating Center. This individual is responsible for making Coordinating Center resources available to the Writing Group. Primary authors and/or their Writing Groups are advised to consult with the Coordinating Center liaison in the initial planning stages for assistance with analysis plans and to ensure that analytic resources are made available in a timely manner.

The Steering Committee may also designate a specific writing assignment for a collaborative publication, e.g., a paper on recruitment and retention activities across the three sites. The Steering Committee determines who should serve as the Primary Author for this publication. The Principal Investigators also recommend individuals at their site who are interested and qualified to contribute to these papers.

6.2 Authorship on Publications

The Primary Author determines the order of authorship on the abstract or publication. All individuals who make a substantive intellectual contribution to the research being described in the publication are included as authors. Authorship is not limited to those who actually wrote sections of the paper. Conversely, a PI is not always included as an author simply by virtue of being the PI. There must be a substantive intellectual contribution to the research being described in the paper.

7. ACKNOWLEDGEMENT OF THE CALERIE COOPERATIVE AGREEMENT

In collaborative publications, the list of authors must be followed by the statement “for the CALERIE Research Group” to acknowledge that this is a cooperative agreement. Sponsorship of the NIA and a listing of all research grant numbers under this cooperative agreement must be provided in the Acknowledgements section of collaborative publications. The grant numbers are as follows: Pennington: 1U01AG020478-01; Tufts: 1U01AG020480-01; Washington University: 5U01AG020487-02; and, DCRI: 1U01AG022132-01.

Sponsorship of the NIA and the corresponding grant number must be provided in the Acknowledgements section for all site-specific publications. Moreover, there must be some reference to CALERIE as a whole. It may appear as a footnote to the title page; or, it may appear under the acknowledgements section at the end of the article. An example statement is, “This paper reports site-specific findings from the XXX site of the CALERIE studies.”

8. PUBLICATION IN THE SCIENTIFIC LITERATURE FIRST

CALERIE investigators affirm that scientific results of the CALERIE studies will not be discussed or presented to the lay community until they have appeared in the scientific literature. An exception to this is talking to the media about papers or abstracts prior to publication, when a firm understanding has been reached that the lay material will only be published on or after the date of scientific publication. In the case of an abstract, the publication date is that of the published program for the scientific conference. For a journal article, this includes the appearance of the paper version of the article in print, or the posting of the electronic version on the journal’s website, whichever comes first.

9. SITE-SPECIFIC PUBLICATIONS AND ABSTRACTS

CALERIE investigators are at liberty to prepare and submit site-specific publications and abstracts without formal review by the PubSc. As discussed in §5, the Coordinating Center is responsible for preparing reports on all publications and abstracts completed and in progress. The Coordinating Center is also required to catalog, distribute, and archive all publications and abstracts prepared by CALERIE investigators. Thus, a copy of the final version of any site-specific abstract or publication must be deposited with the Coordinating Center when it has been accepted.

10. PUBLICATIONS INITIATED BY THE CC AND THE NIA

It is anticipated that papers will be initiated by investigators at the CC and at the National Institute on Aging. These papers may describe, for example, methodological approaches to conducting multi-site investigations or performing collaborative analyses across the sites. Analyses based on data pooled from two or more sites are still considered “collaborative” analyses, and guidelines described for collaborative publications apply in full measure. For any site-specific analysis, the CALERIE investigator at the CC or NIA must obtain the permission of the Principal Investigator at the site whose data are being used. For a collaborative analysis, the CC or NIA investigator must obtain the permission of the Principal Investigators from the centers that provided the data. These permissions must be obtained prior to any use of the data, and would ordinarily be obtained when the analysis proposal is reviewed by the Statistical Analysis Subcommittee.

11. PROPOSALS FOR COLLABORATIVE ANALYSIS

Before collaborative papers are written, a proposal for the analysis to be performed must be reviewed and approved. Once approved, resources can be made available to the research. The following procedures are applied.

1. A writing group, as described in Section 6.1, is formed and proposes a collaborative analysis of interest. This might consist of a CALERIE group already established for the study or an ad hoc writing group. It can also consist of an individual with a particular interest.
2. The writing group prepares a brief “Analysis Proposal” describing the analysis it intends to perform. This is a 1-3 page summary describing the question being addressed, the rationale for this analysis, the study population, the hypotheses of interest, and a brief description of the statistical procedures to be applied, and so on.
3. The Analysis Proposal is submitted to the Statistical Analysis (SA) Subcommittee for consideration and approval. The SA Subcommittee has the option of accepting the proposal or asking for clarifications and changes.
4. Once approved by the SA Subcommittee, the Analysis Proposal goes to the Steering Committee for final approval. The Steering Committee sets its priority against other collaborative analysis activities already approved.
5. Once approved by the Steering Committee, the writing group is at liberty to proceed with the analyses and prepare the subsequent publication.
6. The abstract or publication then comes under the domain of the PubSc to track and ultimately approve the resulting publication as described below.

12. REVIEW PROCESS FOR COLLABORATIVE WRITING

12.1 Abstracts based on Collaborative Analyses

The Publications Subcommittee must review any abstract based on collaborative analysis before it is submitted to a conference or scientific meeting. Because there is typically a deadline imposed by the conference organizer, an expedited review process is prescribed.

1. The primary author submits a copy of the abstract to the CC (e.g., as an e-mail attachment) at least 4 working days prior to the deadline for submission.
2. The CC disseminates the abstract to the members of the PubSc within 1 working day.
3. Members of the PubSc have 2 working days to review the abstract for consistency and scientific integrity.
4. PubSc members vote on the acceptability of the abstract by the 4th working day, with a simple majority vote to approve. Lack of response within the four-day deadline is interpreted as approval.
5. The Coordinating Center communicates the results of the vote to the submitting author by the end of the 4th working day.

12.2 Manuscripts Based on Collaborative Analyses

The Publications Subcommittee must review any manuscript based on collaborative analysis before it is submitted for publication. Because manuscripts are more involved than abstracts, a more detailed review process is prescribed. The process is as follows and must be completed within 10 working days (i.e., two weeks).

1. Primary author submits a copy of the manuscript to the Coordinating Center (e.g., as an e-mail attachment).
2. The Coordinating Center sends a copy of the manuscript to the PubSc members within one working day.
3. PubSc members consider the manuscript and circulate their reviews to the other PubSc members via e-mail, FAX or the CALERIE website within 7 working days.
4. PubSc members have 1 day to consider the reviews and circulate their final recommendation. Lack of response within the timeframe is interpreted as approval.

Possible recommendations include: (a) manuscript approved; or, (b) PubSc approval withheld due to major errors, problems or inconsistencies. An approved paper is returned to the primary author along with the reviewers' comments and any additional material prepared by the PubSc. The primary author can incorporate these recommendations at his/her discretion, and is at liberty to submit the paper for publication. An approval-withheld paper is returned to the primary author, together with the reviewers' comments and any additional material compiled by the PubSc. The author(s) can address the concerns raised by the PubSc or appeal the decision directly to the Steering Committee. Any revised manuscript must be re-submitted to the PubSc and the process begun anew.

Finally, authors are required to bring any manuscript back to the PubSc if it is changed substantially in tone, analysis or conclusions from the original as it moves through the review and revision process with the journal.

13. CONFLICT RESOLUTION PROCEDURES

Conflicts, disputes and differences in opinion concerning types of publication, scope of activities, authorship, and the review process are addressed in the first instance by the Publications Subcommittee. A letter or e-mail message to the Chairman of the PubSc is sufficient to initiate the process. The Chairman attempts to resolve the issue directly. Otherwise, the issue is brought to the attention of the full PubSc and placed on its agenda at its next meeting.

If PubSc is unable to resolve the issue to the satisfaction of the CALERIE investigator, s/he may bring the issue directly to the CALERIE Steering Committee. The Steering Committee, however, serves as the final arbiter of any dispute.

14. SHARING DATASETS AMONG THE SITES

A site is only entitled to data from participants enrolled at its own center. To allow collaborative data from one site to be issued to another site, the Principal Investigators at the two sites must signify, in writing (e.g., in an e-mail message), that they agree to share the data. This would typically occur when the analysis proposal is reviewed by the Statistical Analysis Subcommittee.

15. PUBLIC ACCESS TO STUDY DATASETS

In a policy issued on February 26, 2003 (i.e., NOT-OD-03-032), the NIH affirmed its support for the concept of "data sharing," that is, making data from a research study available to other interested researchers. "We believe that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health ... The NIH expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers." The notice clarifies that "timely release" means no later than the acceptance for publication of the main findings from the final data set. Thus, the NIH agrees that the initial investigators should benefit from first and continuing use. However, they should not have prolonged and exclusive use of the data.

In principle, the CALERIE investigators signify their support for this policy. In practice, however, this support will be tempered by policies at their respective institutions, local IRB regulations, and local, state and Federal laws and regulations (including the HIPAA Privacy Rule). Moreover, in a complex study such as CALERIE, it necessarily takes time to analyze and publish the results.

Thus, inasmuch as local rules, regulations and policies are satisfied, and inasmuch as the proposed analyses do not intrude on analyses and manuscripts being performed or contemplated by CALERIE investigators, we are prepared to share data generated from this study with researchers and scientists qualified to conduct supplementary analyses.

In CALERIE, the relevant data may be those maintained in collaborative dataset(s) at the Coordinating Center, and/or site-specific dataset(s) maintained at the individual sites. Any public data set will have been stripped of all obvious and inadvertent personal identifiers as mandated by HIPAA regulations, and they may be grouped or modified slightly to prevent identification of individual participants. The data released will also be consistent with information provided in the participant's informed consent document. Limited-access dataset(s) and supporting documentation will be provided in an appropriate electronic medium. Documentation may be written in Microsoft Word; the data themselves may be written in SAS export format.