# CALERIE SAMPLE ACCESS AND SECONDARY ANALYSIS STUDIES GUIDELINES

A secondary analysis study involves analysis of the existing data and generation of new data using biological samples (blood, urine, muscle or fat) collected from CALERIE participants and stored in the CALERIE Data Repository. A list of all currently planned analyses by investigators using CALERIE data and samples is maintained on the CALERIE Website in the Ongoing Projects tab. All proposals for secondary analysis studies are reviewed, scored and approved by the CALERIE Steering Committee (SC) and supported by the External Science Committee using the procedure outlined below.

## A. What proposals will be considered?

Investigators are encouraged to conduct secondary data analysis and additional studies using CALERIE dataset and biorepository samples with the stipulation that they be scientifically sound and are consonant with the overall CALERIE goal: ”to test the hypothesis that two years of sustained caloric restriction (CR), involving a reduction in energy intake to 75% of baseline (25% CR), in healthy men aged 21 to 50 and healthy women aged 21 to 47 will result in the same adaptive changes that occur in rodents subjected to CR.”

Investigations that propose the use of CALERIE biorepository samples to address scientific questions duplicative of already existing and approved investigations or addressing questions that do not further the goals of CALERIE will not be further considered and will be returned to investigators.

A data dictionary for the CALERIE database, and a listing of available samples from serum, plasma, PAXgene tubes, urine, muscle and fat is listed at the CALERIE web site. Access to the database and samples will be handled through the CALERIE web site.

## B. The CALERIE Steering Committee (SC)

The SC is composed of investigators from the three original CALERIE clinical sites (Pennington Biomedical Research Center (LSU); Tufts University; Washington University, St. Louis), the original CALERIE Coordinating Center (Duke University) and the National Institutes of Aging (NIA). Meeting quorum consists of all five sites.

## C. The CALERIE External Science Committee (ESC)

The ESC is composed of membership representing a broad spectrum of expertise relevant to CALERIE:

- CR studies in animal models
- Disease risk epidemiology - especially focusing on primordial risk
- Biology of aging
- Metabolic physiology/energy balance/endocrinology
- Molecular predictors of aging: metabolomics/gene expression/epigenetics

Additional membership consists of the two co-Principal Investigators of the sponsoring CALERIE U24 Network Resources Grant. Meeting quorum consists of a minimum of four voting members.

## D. Application process and proposal format

All proposed ancillary studies and secondary data analyses must be submitted to the SC in

time for subsequent SC review prior to submission to a funding agency. The Committee meets a minimum of quarterly for consideration of studies. Studies submitted for review less than 30 days prior to a funding application submission deadline may not receive an approval letter for inclusion in the application.

An investigator who wishes to conduct an ancillary study or perform secondary data analysis will submit a proposal to the chair of the SC who will track the process through the SC. All materials should be submitted as a single pdf.

Please include a Research Proposal with the suggested format:

- General Research Proposal
- Structured Abstract
- Background and Rationale
- Specific Aims
- Methods: Justify the requested sample numbers (e.g. sample size) and amounts (e.g. volume). Describe the laboratory performing the assays, the laboratory methods, and quality control.
- Literature References

When the application is complete, the chair will send the proposal to the Committee for review as outlined, below.

**E. Review process**

The following criteria will be used by the CALERIE SC to make a decision about whether to approve a proposed study:

- The proposed study addresses an important scientific problem related to the objectives of CALERIE;
- The aims are achievable and advance scientific knowledge in the topic area
- The study is not unnecessarily duplicative of other ongoing studies/analyses.
- Proposed methods are scientifically sound, feasible and reliably measure the proposed outcomes.
- The requesting investigators are appropriately trained and well suited to carry out the project, and their experience level is appropriate for the proposed work.
- Required equipment is available.
- A funding source has been identified if not seeking pilot funding.
- The scientific environment in which the work will be done contributes to the probability of success.

After discussion, the members of the ESC will reach consensus and/or bring the proposal to a vote.

**Notes / special situations:**

A letter will be provided by the SC Chair to the study investigator upon approval of the completed funding application. The investigators will be required to sign the data/sample use agreement (Appendix 1) prior to receiving access to CALERIE data and / or biospecimens.

## F. IRB approval

IRB approval is not required to submit a proposal to the CALERIE SC. However, access to samples and data will require approval of the local IRB of the proposing investigator.

## G. Funding

All studies must be approved by the SC before funding applications are submitted to the funding agencies. Proposals for funding must include coverage of all the costs, including administration, data access costs, and sample access and mailing costs. The cost of sample access and mailing can be obtained through consultation with the Biorepository Director at the University of Vermont (contact information will be available at the CALERIE Web page). An ancillary study investigator may not enter into any verbal or written agreement or contract with industry or private individuals that will provide funding for anything related to CALERIE without prior review and written approval from the CALERIE Emerging Science Committee.

## H. Changes after approval

The proposing investigator is required to provide annual (semi-annual) reports to the SC informing the committee about the study progress. Studies supported by the National Institutes of Health (NIH) may submit their annual progress reports to the CALERIE SC at the deadlines required by the funding Institute.

## I. Data

The PI of the ancillary study will be responsible for analysis of ancillary study data although CALERIE Network grant resources can be employed to assist with data analysis. The investigator should request funds for such analysis from the funding agency. The study PI will retain all rights to the publication and/or distribution of the data. Upon publication of the results of the study, or a maximum of 12 months after termination of the grant under which the study was conducted, all generated data should be submitted to the CALERIE data repository.

## J. Data analysis, publications and presentations

All the publications, presentations and abstracts must acknowledge the CALERIE study (U24- AG047121).