Chapter 21

Publications and Policies Procedures

PUBLICATIONS AND PRESENTATIONS (P&P) COMMITTEE

Charge to the (P&P) Committee: The P&P committee is to establish and carry out policies promoting collaborative, high quality dissemination of study findings in a timely and accurate manner. It proposes policy for presenting and publishing LLFS data, including writing group membership, authorship, presentations, and internal manuscript reviews. It coordinates the LLFS publication process to ensure that study results are disseminated in a timely, accurate, and clear manner. The committee maintains an up-to-date list of LLFS presentations and publications and routinely reviews the progress of LLFS publications and presentations.

Composition of the P&P Committee. The membership of the P&P Committee is composed of representatives from each study unit, including the field centers, DMCC and NIA. The Committee maintains a list of the interests and expertise of all LLFS investigators in categories reflecting the major areas of publications and calls on LLFS investigators to provide statistical and content reviews of publications within their areas of interest and expertise.

Committee Duties regarding Scientific Publications: The duties of the P&P Committee are listed below and concern all scientific and public communication for the LLFS study. It will also review publications stemming from ancillary studies to the LLFS study headed by both internal and external principal investigators.

- Recommends to the LLFS Steering Committee policy and procedures for proposals, authorship, review and approval of all scientific and public communications regarding LLFS to outside groups.
- Recommends to the Steering Committee topics of scientific priority.
- Reviews and approves all proposals for LLFS-related publications or abstracts and writing groups.
- Monitors the progress of writing of each scientific paper to ensure publication in a timely fashion.
- Performs an internal review of manuscripts prior to submission for publication, The P&P Committee ensures that each paper is reviewed prior to submission for statistical analytic methods and content and for accuracy and consistency of the data analysis with other LLFS documents and publications. Recommends approval as is, approval with minor revisions, request for major revisions or disapproval.
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- Performs other writing, reviewing, or editing tasks assigned by the Steering and Executive Committees.
- Ensures that all publications and presentations acknowledge the funding agency: The Long Life Family Study (LLFS) has grant support from the National Institutes of Health, DHHS, through the National Institute on Aging (Grants 5U01AG023744, 5U01AG023755, 5U01AG023749, 5U01AG023746, 5U01AG023712).

Rationale for Authorship Rules: Authorship should represent each field center, the coordinating center, the Core Laboratory if assays were performed by the Core Laboratory and the project office by requesting at least one author from each study unit at the proposal stage who will contribute to the manuscript to a significant extent. There are several categories of scientific publications and presentations listed below. Each category has different rules for authorship. These range from publications that address the primary hypotheses of the

study (which may have authorship by the entire research group) to other types of publications with named authors. The authorship rules balance the need to recognize the contributions of all members of the LLFS Research Group and staff with the need to recognize individuals for specific contributions to certain types of publications and presentations.

DEFINITIONS OF TYPES OF COMMUNICATIONS

Communications from LLFS and LLFS ancillary studies may be classified as a press release, interview, public web site posting, abstracts for presentations or publication. All of these communications, except press releases and presentations, must be reviewed and approved by the P&P Committee, or in some cases specified below—by the P&P Chair before release or submission.

Press Releases and Interviews: A press release is defined as a document containing LLFS unpublished data given to radio, television, newspapers, popular periodicals, or scientific journals (including publications of pharmaceutical companies or professional organizations) not refereed and/or peer-reviewed. There also may be press releases for recruitment purposes. An interview is any discussion with a member of the press, a science writer, or a radio or television commentator, who in turn provides information for public dissemination. . Please submit published press releases and interviews to LeAnne for tracking purposes (l.kniepkamp@wustl.edu).

Web Site Posting: Published materials will be posted to the LLFS website. Review of items to be posted will take place on the bi-weekly P&P call.

The study will also maintain an internal website. The P&P committee requires posting of the abstract and paper proposals regarding the design, methods, and participant characteristics for use in the development of manuscripts and presentations. This internal website is available only to LLFS staff and investigators. The materials on the internal website will be posted by the coordinating center staff and do not require P&P committee review and approval.

Presentations: A presentation is defined as the delivery of unpublished LLFS information to scientific, professional or public groups either orally or in poster format. A presentation may include an abstract to be published by the group to which the presentation is made. The P&P Committee must approve all abstracts prior to submission. In rare circumstances, however, the Executive PI committee may approve abstracts. Proposed abstracts should be submitted at least two weeks prior to the due date, in order to allow time for revisions if not approved as is. The P& P Committee may request a review from the Data Analysis Committee to insure data accuracy, and may obtain reviews from other investigators if they deem it necessary. If the abstract is accepted for presentation, the investigator who submitted the abstract should notify the P&P Committee. It is permissible to submit previously cleared abstracts to other meetings; with notification of the P&P committee. The P&P committee will not routinely review slides prior to presentation, but may request copies of key presentations for the internal web site.

Publications: A publication is defined as any document (any manuscript including chapters and books, other than an abstract) submitted to a professional peer-reviewed journal, medical textbook, or any popular periodical with national circulation.

SCOPE OF RESPONSIBILITY FOR THE PUBLICATION POLICY

It is the intention of the LLFS group that the policy described herein applies to all public and scientific communication of unpublished data that result from any LLFS or LLFS-related activity. This policy covers communication from substudies and ancillary studies, as well as the activities conducted by the LLFS Research Group as a team effort. All investigators collaborating in the LLFS study agree to abide by the policies and procedures.

Investigators, such as those who work for federal agencies, whose employers require that they comply with other publication policies, must also abide by these policies and procedures. If such an individual is required to submit publications for review prior to publication, he or she does so in addition to following the review procedures described here. In any case, LLFS does not relegate review or approval for publication or presentation to another agency or institution. However, comments or suggestions from the federal agency review should be transmitted to all authors for consideration.

CATEGORIES OF COMMUNICATIONS AND AUTHORSHIP OF PUBLICATIONS

The following categories of communications apply to scientific presentations and publications. Press releases, interviews, and presentations (without published abstracts) do not have authors. When presentations are accompanied by published abstracts, the authorship rules for the abstracts are the same as for other types of publications, as described in this Section. "Core" publications (Category A described below) do not have named authors (group authorship). For Categories B and C, when authors" names are listed, they are those of the members of the writing group (see below).

Three categories of communications have been designated:

Category A: *Publication of LLFS results deemed "core" publications have a few named authors (one per each field center and one per coordinating center = 5) on behalf of the LLFS* The publication should acknowledge LLFS in the paper with " On Behalf of the Long Life Family Study" and notification of review will be sent to the Executive Committee.

Category B: Other publications using data gathered by all LLFS members are written by designated writing groups whose members are named as authors. The writing group members are the publication authors, with the lead author being the writing group leader. Author designation is "A.B., C.D., E.F. and the LLFS Research Group." For all Category B papers, the paper should also acknowledge LLFS in the paper with "On behalf of the Long Life Family Study".

Category C: This category includes publications from ancillary studies and sub-studies. A sub-study includes only some of the sites or a sub-sample, but is supported with the core study cooperative agreement funds. An ancillary study collects new data not supported by cooperative agreement funds, usually via an ancillary grant. The authors of publications describing work by a subset of clinical sites may include members of the particular centers involved in the sub-studies as well as other LLFS Investigators, when appropriate. The named authors are the writing group members for the publication, Substudies should include " On behalf of the Long Life Family Study while ancillary studies should acknowledge the support from NIH to LLFS . Sub-studies describing a sub-sample from all clinical sites are considered Category B.

Category D: This category includes publications resulting from involvement in consortia, as part of a meta-analysis or replication effort. The proposal will be from the LLFS investigator representing LLFS as the point of contact for the consortia. As per most consortia, authorship will be limited to ~4-8 co-authors per study. Thus for this work it is imperative that authorship be evenly distributed among the field centers and DMCC. The purpose of reviewing proposals and manuscripts in Category D is to protect the integrity of LLFS data and broad scientific goals. If the lead author of the consortia work is an LLFS investigator, both proposal and manuscript will go through regular P&P review process. If the LLFS investigator is not the consortia lead, the proposal will go through an expedited process (either approve or not approved), and the subsequent manuscript will also go through an LLFS review. Support from LLFS should be acknowledged in the paper.

Use of LLFS Data for Theses by Graduate Students: All requests for use of LLFS data by students are to be reviewed by the P&P Committee. Students requesting use for LLFS data must have a "sponsor" who is a LLFS investigator. LLFS data may not be used by students if the data relate to major LLFS papers in progress or if the P&P Committee deems that data to be necessary for a future major paper. If the P&P Committee recommends approval for the use of the requested data, a writing committee is to be established and is to include the student as convener of the committee. The student's sponsor is to report the student's progress to the P&P Committee at least annually. The student must include in the completed thesis a statement acknowledging LLFS for use of the data.

It is the responsibility of the LLFS "sponsor" to ensure that the thesis accurately reflects the conduct and data from LLFS, as dissertations are technically available to the public without having gone through the P&P review process. If the data used for the thesis includes data from all LLFS sites, the standard LLFS publication policy for publications that would fall into Categories A, B or D, including a request for co-authors from all sites, is to apply to any material published from the thesis. If the data used for the thesis is restricted to the student's site or to a subset of clinical sites, then the study would be considered a Category C (sub-study) paper and the policies of Category C apply: Those procedures specify that th e authors of publications describing work by a subset of clinical sites may include members of the particular centers involved in the sub-studies as well as other LLFS Investigators, when appropriate. The named authors are the writing group members for the publication, Sub-studies should include " On behalf of the Long Life Family Study. LLFS reserves the right to proceed with preparing a paper for publication on the thesis topic if, in the view of the P&P Committee and the student's sponsor, the student has not made reasonable progress in completing the thesis or the paper. At the point when work is being prepared for publication, the student should invite participation form members of the other sites

CATEGORIES OF COMMUNICATIONS AND AUTHORSHIP OF PUBLICATIONS

Category E. This category includes methodology papers where LLFS data are primarily used to test the methodology. The lead author should submit a proposal to the P&P Committee. After the proposal has been approved and the analyses done, a presentation should be made to the R&D Committee. The completed paper will be reviewed by the P&P for the accuracy of the description of LLFS data and conclusions.

Manuscripts from ancillary studies that require LLFS data from all clinical sites are published as Category B. For ancillary studies to LLFS that analyze data gathered from only a portion of clinical sites, Category C applies. For Category C ancillary studies, the authors may include members of the particular center(s) involved in the ancillary study as well as other LLFS investigators, where appropriate. At least three LLFS investigators must be included on all manuscripts that use LLFS data (either Category B or Category C manuscripts). Support from LLFS should be acknowledged in the paper or say " On behalf of the Long Life Family Study

Other LLFS Personnel as Authors: The writing group for a LLFS manuscript may include trainees, study coordinators, and other LLFS personnel as authors, providing that each author was involved in the analysis or writing of the paper. Depending on her/his involvement, such an individual may be first author on a paper.

Proposals from Outside Investigators, including Ancillary Studies: Outside investigators (not funded by LLFS) will be able to participate in the writing of manuscripts through collaboration with a LLFS investigator. The sponsoring investigator will send a cover letter of introduction with the proposal to the P&P committee. The sponsoring investigator will facilitate access to the study policies and procedures. The Coordinating Center will release data to an outside investigator upon approval of the proposal along with documentation of IRB approval, Data Distribution agreement, and human subject certification at the proposer's home institution. The ancillary study must be proposed with an LLFS investigator as a co-investigator and at least three LLFS investigators must be included as co-authors on these manuscripts.

Abstract Authorship: The categories and authorship rules for abstracts accompanying presentations are as above, except that Category A abstracts, when required, have at least one named author (the first of whom is usually be the person making the presentation), to be listed as: A.B. Smith, C.D. Garcia, E.F. Johnson, and the LLFS Research Group. A full list of members of the LLFS Research Group is not included.

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" On behalf of the Long Life Family Study…" Every clinical site and all collaborating entities are listed as participating centers. Those scientific, federal, or commercial organizations providing funding are also recognized. (U01 numbers and study acknowledgement in Appendix

Investigators List of Proposal Submission Procedures

1- Investigators submit their proposal on Confluence then email LeAnne (l.kniepkamp@wustl.edu)

   Proposal page:
   https://dsgproject.dsg.wustl.edu/pages/viewpage.action?pageId=1245289

2- As co-authors are added, Investigators will solicit their comments/suggestions.

3- Investigators will incorporate co-authors comments in Confluence, **please include a statement of assurance that you have solicited and address coauthor statements on your proposal page.**

4- Email LeAnne (l.kniepkamp@wustl.edu) when your proposal is ready to be reviewed by P&P

NOTE: All communications regarding a particular proposal should be on that proposal's Confluence page. Because co-authors are tagged, they can receive notifications via confluence if any changes are made. This is to encourage contribution among coauthors and ensure everyone is aware of edits/changes. We should move away from email conversations. All abstracts, presentations, supplemental materials, conversations regarding revisions, versions of a paper, and the final publication will be tracked on this page. If emails are exchanged regarding your paper, please cc LeAnne so that she can track those emails in your proposal's Confluence page.

TIMELINE- The entire process takes approximately 4 weeks.

P&P calls are 1st and 3rd Thursday of the month.

LeAnne will distribute all new proposals to ALL LLFS soliciting co-authors every Monday morning. Please have **your proposals to LeAnne by 10 AM Eastern on Monday**. If a proposal comes in Tuesday-Sunday, LeAnne will hold on to it till Monday's distribution.

LeAnne will distribute completed proposals and manuscripts to the P&P committee one week prior to each call.

Complete proposals (with coauthor feedback) must be **submitted to LeAnne by Tuesday ONE WEEK prior to the scheduled P&P call,** otherwise it will be bumped to the next call.

Example Timeline:

-Lead Author uploads Proposal and emails LeAnne Thursday, March 1, 2018.
-LeAnne distributes Proposal the following Monday, March 5 at 10 am.
-Coauthors express interest over the next week (~Monday March12)
-Lead author to solicit coauthor responses, incorporate in proposal and email LeAnne when the final version is ready to be reviewed by P&P (~Tuesday March 13)
----NOTE, Tuesday 3/13 till the next call Th 3/15 does not allow P&P enough time to review, thus this proposal would be bumped to the next call
-Proposal reviewed by P&P Thursday, April 5, 2018
-Nicole to email Lead Author with P&P results within 2 days of call.

NOTE: Full lists of approved proposals will be distributed quarterly: Jan, Mar, June, Sept

MANUSCRIPTS

Draft manuscripts must be circulated to all co-authors prior to submission to P&P.

Lead Authors must submit a statement of assurance that all coauthors comments were addressed.

Manuscripts may only be submitted to a journal once the draft manuscript with coauthor comments have been submitted and approved by P&P.

Complete manuscripts (with coauthor feedback) must be **submitted to LeAnne by Tuesday ONE WEEK prior to the scheduled P&P call,** otherwise it will be bumped to the next call.

Technical manuscripts will be sent to internal reviewers prior to P&P review and will be bumped to the following call.

CLOSE THE LOOP- Inform DMCC when your paper has been published. Please provide pubmed link, Title and LLFS Tracking Number.

NOTE: Full lists of approved proposals will be distributed quarterly: Jan, Mar, June, Sept

Submission of Analysis Plans: An analysis plan should be submitted for each proposed abstract and manuscript. Generally one abstract should correspond to one manuscript. Thus one analysis plan should cover both the abstract for presentation and one manuscript for journal submission. The analysis plan should be prepared after checking the internal website for potential overlap and if any potential overlap is noted, this should be discussed directly by the respective investigators. This discussion should be reflected in the plan. No more than three active plans will be permitted per first author. However, once a manuscript based on a proposal has been submitted to P&P, an additional proposal may be made. The lead author of a new proposal should draft the analysis plan and circulate it to PIs and potential co-authors across all sites for input. Each study unit should be represented on Category A, B and D publications. Once all coauthors agree on the analysis approach, the plan should be submitted to P&P for review and approval. Proposals will not be approved by P&P until the first or corresponding authors have documented that they have requested input for interested co-authors for all sites. The Coordinating Center will inform the LLFS Study Group of new proposals at the time of their submission and approved proposals quarterly via email. Category A, B abd D aanlysis plans which do not include a co-author form each LLFS study unit will require an explanation for their exclusion before P&P approval.

Proposal Template: The template for submission is in the appendix and on the LLFS internal web-site and should include:

- Name and contact info
- Title/topic
- Proposed coauthors
- Meeting and abstract deadline if abstract is planned
- Target journal if known
- Hypothesis or goal
- Brief background/justification including any discussion of any apparent overlap
- Specific primary data to be used
- Analysis approach
- Approval date

Once approved the analysis plan remains active for 12 months. P&P will facilitate manuscript completion if progress is delayed. In some cases, a change in first author may be requested by the first author or by P&P to facilitate completion of a manuscript.

Press Releases and Interviews: A press release or interview may be appropriate with a presentation or publication announcing a study result of great public interest. Press releases and interviews on papers and abstracts that use materials that have already been approved by the P&P Committee do not have to be approved for each subsequent use but are developed and managed by the lead author of the paper or abstract. Should a clinical center be solicited for information other than that detailed in the approved materials or centrally prepared press releases, the clinical center should refer the soliciting party to the Executive Committee

PUBLICATIONS

The following procedures apply to all publications (categories A through D?) whether submitted or invited.

Writing Group: The P&P Committee approves a writing group of at least 1 one coauthor from each LLFS study unit including the field centers, Coordinating Center and Core Laboratory for each proposed publication. Members of the writing group are drawn from the members of the LLFS Research Group at large. Members of the LLFS Research Group may request to join the writing team and are included to the extent practical. Each proposal for an A or B paper should include at least one representative of each study

site, except in unusual circumstances. The P&P Committee approves (by simple majority vote) the final constitution of the writing group While the leader/lead author of the writing group is usually the individual proposing the paper, this may not necessarily be the case.

Responsibilities of the Writing Group Chair[1]

Overall Responsibilities: During all phases of manuscript development, coordinate writing group efforts and ensure timely preparation of the manuscript according to the production timeline.

Detailed Charges:

- Communicate with the Writing Group members, the CC, the P&P Committee, and the target journal editors.
- Prepare outlines.
- Oversees data analyses.
- Assign tasks/set deadlines for Writing Group members.
- Conduct periodic Writing Group meetings or conference calls.
- Circulate manuscript drafts to Writing Group members.
- Establish consensus among Writing Group members concerning target journal.
- Establish authorship order based on level of effort/input.
- Submit final manuscript draft to P&P Committee.
- Submit approved manuscript to target journal following final approval by P&P Committee.
- Submit reprint of published article to the LLFS Coordinating Center for posting on the internal Web site.

[1] Failure of the Writing Group Chair to meet these responsibilities could result in dismissal as Chair and replacement with another Writing Group member or LLFS Investigator committed to fulfilling these functions.

Responsibilities Writing Group Members[2]

Overall Responsibilities:

- Actively participate in preparation of the manuscript.
- Fulfill assigned writing group tasks in a timely manner.
- Complete all appropriate responsibilities noted above.

[2] Failure of a Writing Group member to meet these responsibilities could result in dismissal from the Writing Group and replacement with another LLFS Investigator committed to fulfilling these functions.

Writing Group Leader: The writing group leader should submit to the P&P Committee a one to two page description of the paper, including hypotheses, study sample, variables to be examined and analytic methods, using a cover sheet found on the web for submitting proposals. The P&P Committee reviews and approves each proposal The P&P Committee monitors progress of the writing group toward publication. If timely progress toward publication is not made, the responsibility for writing group leadership may be reassigned by the P&P Committee.

Journal Identification: The writing chair informs the P&P committee of the planned target journal. The P&P committee may propose a target journal or endorse the recommendation of the writing group.

Initial Manuscript Review: The P&P Committee designates at least two reviewers for initial internal review of all manuscripts, including one member of Analysis Committee and one LLFS study investigator (may or may not be a P&P member).

The P&P Committee may also request review of the programming of the data analyses by the Data Analysis Committee. To facilitate this, documented data underlying these manuscripts may be requested.

Approval for Category A and B Manuscripts: Following review, the manuscript of a Category A or B publication must be approved by a simple majority of the P&P Committee. If deemed appropriate by the P&P committee, the manuscript will be forwarded to the Executive Committee with reviewer comments. In addition, if investigators from NIA are included as authors, the DMCC will also forward the manuscript to NIA for clearance. After Executive Committee approval and NIA clearance, if required, the manuscript may be submitted to the journal by the primary author. The leader of the writing group usually serves as corresponding author. After the manuscript is accepted for publication, the revised final version of the manuscript must be submitted to the DMCC. Along with tracking proposal and manuscript tracking number.

Approval for Category C Publications: Manuscripts of Category C publications are distributed as above, and comments are sent to the lead author of the writing group and to the P&P Committee. Submission of a Category C publication requires approval of a majority of the P&P Committee, and if deemed appropriate, Executive Committee approval and NIA clearance. After the manuscript is accepted for publication, its revised and final version must be submitted to the DMCC for posting on the website.

Page and Reprint Charges: The first author is responsible for any page and reprint charges for manuscripts. Advance approval of use of study funds must be obtained from the PI of the study site. Page and reprint charges for ancillary studies should be funded separately.

Use of LLFS Data for Theses by Graduate Students: All requests for use of LLFS data by students are to be reviewed by the P&P Committee. Students requesting use for LLFS data must have a "sponsor" who is a LLFS investigator. LLFS data may not be used by students if the data relate to major LLFS papers in progress or if the P&P Committee deems that data to be necessary for a future major paper. If the P&P Committee recommends approval for the use of the requested data, a writing committee is to be established and is to include the student as convener of the committee. The writing committee is to take no action regarding the paper until the student has completed and defended the thesis, provided this occurs in a reasonable length of time, to be determined on a case-by-case basis. The student's sponsor is to report the student's progress to the P&P Committee at least annually. The student must include in the completed thesis a statement acknowledging LLFS for use of the data.

When the thesis has been completed, as determined by the sponsor, the entire writing committee is to proceed to prepare the paper(s) for publication. It is the responsibility of the LLFS PI "sponsor" to ensure that the thesis accurately reflects the conduct and data from LLFS, as dissertations are technically available to the public without having gone through the P&P review process. The standard LLFS publication policy is to apply to any material published from the thesis. LLFS reserves the right to proceed with preparing a paper for publication on the thesis topic if, in the view of the P&P Committee and the student's sponsor, the student has not made reasonable progress in completing the thesis.

Use of LLFS Data for Grant Application or Contract Proposal: LLFS data that have not been previously published but which are needed for grant applications or contract proposals must have prior approval for use by the LLFS Executive Committee.

DISAGREEMENTS WITH THE REVIEW

A member of the LLFS Research Group may appeal, in the case of disagreement with the P&P Committee, concerning: 1) the classification of a communication, To initiate an appeal, the first author should initially discuss the issue with the Chair of the P&P Committee to clarify why the disputed judgment was made. If this does not satisfactorily resolve the matter, the claimant should send a letter of appeal (supported by appropriate documentation) to the entire P&P Committee. The P&P Committee reviews the response and responds within four weeks of receipt of the appeal. A further appeal may be made to the chair of the Executive Committee in exceptional circumstances. A decision of the Executive Committee regarding a disagreement is binding.

OWNERSHIP OF DATA

For purposes of publication and presentation policies, study data are defined as all data specified in the Manual of Operations pertaining to participants enrolled in LLFS. Subjects evaluated for eligibility but not enrolled (for whatever reason) are eligible for other studies. Any data obtained during the screening and eligibility process of LLFS, however, can be presented or published only according to the policies herein. Any data obtained during the course of ancillary or substudies can be presented or published only according to the policies herein.

LLFS study data are owned jointly by the individual clinical centers, the NIA, and the Data Management and Coordinating Center and are distributed to the investigators by the DMCC. The various centers make no use of study data nor disclose them to any other parties except as specified in the Protocol or Manual of Operations, unless such use or disclosure is approved by a majority of the Executive Committee.

For approved ancillary studies and sub-studies, the LLFS DMCC provides to the ancillary study Principal Investigator (PI) a cleaned data set of approved data relevant to the ancillary study. Only data that have been approved by the Executive Committee may be released. The time points for data release must also be approved by the Executive Committee. The ancillary study PI is responsible for providing the coordinating center with a cleaned data set of ancillary study-specific data within one year following the completion of data collection in the ancillary study. Ownership of data is thus shared by the ancillary study center and the coordinating center. These data will be made available to other investigators after the primary aims of the ancillary study are completed and published or after completion of the ancillary study funding including renewal or no-cost extension whichever is earlier.

When the DMCC ceases to function as an analytic resource to LLFS (i.e., funding terminates), it releases a fully documented copy of all LLFS data to each clinical center and the NIH. Public policy regarding release of data is under development. Decisions regarding disclosure of data to other parties, such as pharmaceutical companies or the FDA (beyond the required reports), shall be determined by the Executive Committee, subject to NIH 3rd party agreement regulations. Confidentiality of individual participants is to be maintained with all releases of data.

INDUSTRY POLICY

The LLFS study group welcomes donations from industry sources that aid in the conduct of the study protocol. Potential sources of study-wide donations should not be contacted directly by LLFS personnel without first receiving clearance from the LLFS Executive Committee.

Chapter 21: Appendix 1a

A Collaborative Study, Including:

Boston University Medical Center
Columbia University
University of Pittsburgh
University of Southern Denmark
Washington University School of Medicine

Sponsored by:

National Institute on Aging

LONG LIFE Family Study
Data and Materials Distribution Agreement
for Investigators not Affiliated with the LLFS

The undersigned parties hereby enter into this Distribution Agreement as of the date specified on the final page hereof.

PRELIMINARY STATEMENT

The LONG LIFE Family Study (LLFS) investigators with support from the National Institute of Aging (NIA), have collected biologic materials and clinical data from the participants in the LLFS. This phenotypically and genetically well-characterized population represents a valuable scientific resource. Optimizing the informativeness and use of this resource on a scale commensurate with its importance will require a large and concerted effort, which may exceed the research capacity of currently available LLFS investigators. The investigators recognize their responsibility to the public in general, and to the scientific community in particular, to encourage rapid scientific progress by using these resources, subject to appropriate terms and conditions.

Blood samples and clinical data collected by the LLFS have been stripped of all personal identifiers, but the familial nature and the geographic specificity of the sites at which the study subjects were drawn requires vigilant efforts to avoid the inadvertent or deliberate individual identification of some subjects. To protect the confidentiality and privacy of these participants and their families, investigators granted access to these data and materials must adhere to the requirements of this Distribution Agreement. Failure to comply with this Distribution Agreement can result in denial of further access to data and samples from the LLFS and other studies supported by the NIA. Violation of the confidentiality requirements of this agreement is considered a breach of confidentiality and may leave requesting investigators liable to legal action on the part of LLFS participants and their families, or the universities collaborating in the LLFS, or the U.S. Government.

The LLFS investigators have made a substantial and long-term contribution in establishing and maintaining a database of high quality. The investigators encourage appropriate collaborative relationships of outside investigators with the LLFS, and to ensure that the contribution of the LLFS investigators is appropriately acknowledged. The LLFS further seeks to promote the development of valuable discoveries and inventions beneficial to the public health based upon use of the LLFS repository of valuable materials and dat

DEFINITIONS

For purposes of this agreement:

1. "Clinical Data" refers to data, and associated records, collected and recorded from LLFS subjects through periodic examinations and follow-up contacts conducted in the LLFS;

2. "Biological Materials" refers to blood samples and products thereof, including immortalized lymphocytes and extracted DNA, collected and prepared in the LLFS;

3. "Genetic Analysis Data" refers collectively to "Molecular Genetic Data" and "Linkage Analysis Data" as these terms are defined below;

4. "Molecular Genetic Data" consists of data derived from the analyses of DNA samples contained in Biological Materials including, but not limited to, genotyping analysis, anonymous marker polymorphisms, single nucleotide polymorphisms, DNA sequence information, mutation analysis and other genetic analyses.

5. "Linkage Analysis Data" consists of data derived from statistical analyses linking Molecular Genetic Data with Clinical Data including, but not limited to, genetic linkage analysis, transmission disequilibrium analysis, haplotype relative risk analysis, and other statistical genetic techniques.

RECIPIENT

_____ , a [non-profit] OR [for-profit] corporation organized under the laws of the State of _____ with a principal address at _____ ("Recipient") requests access to LLFS Clinical Data, Genetic Analysis Data, and/or Biological Materials at its sole risk and at no expense to the LLFS or any of the universities collaborating in the LLFS.

AGREED TERMS AND CONDITIONS

It is mutually agreed as follows:

1. Biological Material. The LLFS investigators agree to transfer to Recipient the Materials described below for use by the Recipient's principal investigator named below ("Principal Investigator") to conduct the research described in paragraph 4 below. These Biological Materials (including numbers of samples and whether samples are unique or immortalized) are described as follows: _____
_____
_____

2. Clinical Data. The LLFS agrees to provide Recipient with Clinical Data described as follows: _____
_____
_____

3. Genetic Analysis Data. The LLFS [and _____ University] agree to provide Recipient withGenetic Analysis Data, if available, described as follows: _____

_____

_____

The LLFS will provide Recipient with the name and address of any and all other Investigator(s) who generated such "Genetic Analysis Data."

4. Research Project.

a. This Biological Material, Clinical Data and/or Genetic Analysis Data will be used by Recipient's Principal Investigator solely in connection with the following research project ("Research Project"), specifically described below or in an attached Exhibit A: _____

_____

_____

_____

b. The Research Project (circle one); [does][does not] involve LLFS investigator(s) as co-investigator(s). If the Project does involve LLFS co-investigator(s), their names are: _____

_____

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_____

and the work they will perform is described below or in an attached Exhibit: _____

_____

_____

_____

c. This Distribution Agreement covers only the above-described Research Project. Recipient will submit a completed Distribution Agreement (this document) for each research project for which Clinical Data and Biological Materials are requested.

5. Non-transferability. This Distribution Agreement is not transferable. Recipient agrees that substantive changes made to the Research Project described above, and/or appointment by Recipient of another Principal Investigator to complete the Research Project, require execution of a new Distribution Agreement in which the new Principal Investigator and/or new Research Project are designated.

6. Publication. Prompt publication of the results of the Research Project is encouraged. Recipient agrees to provide to the LLFS a copy of any abstract ten (10) days in advance of submission for publication and any manuscript thirty (30) days in advance of submission for publication, in order to permit review and comment, and ensure compliance with the confidentiality requirements of this Agreement.

7. Acknowledgments. Recipient agrees to acknowledge the contribution of LLFS investigators in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Clinical Data and Biological Materials.

a. Collaborations/Acknowledgments. If the Research Project involves a collaboration with LLFS co-investigators (see paragraph 4 above), then Recipients will acknowledge LLFS co-investigators as co-authors, as appropriate, on any publication. In addition, the Recipient will use the first acknowledgment printed below.
b. Other Studies/Acknowledgments. If the Research Project does not involve a collaboration with LLFS co-investigators (see paragraph 4 above), then the manuscripts, upon submission pursuant to paragraph 6 above, will be reviewed by LLFS investigators for scientific content and consistency of data interpretation with previous LLFS publications. If Recipient agrees to incorporate significant comments from the review, Recipient will use the acknowledgment printed below.

"The LLFS is supported by the National Institute on Aging (NIA). This manuscript has been reviewed by LLFS investigators for scientific content and consistency of data interpretation with previous LLFS publications and significant comments have been incorporated prior to submission for publication."

If Recipient does not agree to incorporate significant comments from the review, Recipient will use the acknowledgment:

"The LLFS is supported by the National Heart, Lung, and Blood Institute (NIA). This manuscript was not prepared in collaboration with investigators of the LLFS and does not necessarily reflect the opinions or views of the LLFS, the NIA, or the universities participating in the LLFS."

c. Acknowledgments/Genetic Analysis Data. If Genetic Analysis Data are received, the Recipient agrees to acknowledge the contribution of LLFS investigators and/or the investigator(s) who derived such data in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of such Genetic Analysis Data.

8. Non-Identification. Recipient agrees that Biological Material and Clinical Data will not be used, either alone or in conjunction with any other information in any effort whatsoever to establish the individual identities of any of the subjects from whom Clinical Data or Biological Materials were obtained.

9. Use Limited to Research Project. Recipient agrees that Clinical Data and Biological Material, its progeny, and unmodified or modified derivatives thereof will not be used in any experiments or procedures that are not disclosed and approved as part of the Research Project.

10. Use in Human Experimentation Prohibited. Recipient agrees that Biological Material, its progeny, and unmodified or modified derivatives thereof will not be used in human experimentation of any kind.

11. Compliance with Subjects" Informed Consent. Recipient agrees that the Clinical Data and Biological Material, its progeny, and unmodified or modified derivatives thereof will not be used for any purpose contrary to the subjects" applicable signed informed consent document(s). It is the responsibility of the Recipient's Principal Investigator to consult with the LLFS investigators to ascertain, specifically and in detail, the terms and conditions of applicable LLFS informed consent documents.

12. No Distribution, Avoidance of Waste, Return of Materials. Recipient agrees to retain control over Clinical Data, Genetic Analysis Data, and Biological Material, its progeny, and unmodified or modified derivatives thereof, and further agrees not to transfer Clinical Data, Genetic Analysis Data or Biological Material, its progeny, and unmodified or modified derivatives thereof, with or without charge, to any other entity or any individual. Recipient agrees, in handling the Biological Materials, to make reasonable efforts to avoid contamination or waste of the samples. When the Research Project is completed, or three (3) years have elapsed from the effective date of this Distribution Agreement, whichever occurs first, the Clinical Data, Genetic Analysis Data, and Biological Material will be either returned to the LLFS, or disposed of as mutually agreed upon by LLFS investigators and Recipient, unless an extension of this Agreement is obtained.

13. Recipient's Resulting Genetic Analysis Data to be Provided to LLFS Investigators. Recipient agrees to provide the LLFS with a report every twelve (12) months during the term of this Agreement containing Genetic Analysis Data derived by Recipient, in the performance of the Research Project. Such report will cover all Genetic Analysis Data derived by Recipient up to six (6) months before the reporting date. Recipient agrees that the LLFS may distribute these data to qualified scientific investigators requesting access through established NIA procedures and completing a signed Distribution Agreement comparable to this Agreement. Recipient will provide Genetic Analysis Data, indexed by genotyping ID number in the precise electronic format specified by NIA. When genotyping has been conducted, DNA marker names and allele sizes in numbers of base pairs will be provided for each individual subject as indexed by LLFS subject ID number; descriptive information about each typed marker that includes marker name, allele sizes in numbers of base pairs and corresponding frequencies, relative distances in Megabases and in Centimorgans, marker heterozygosity, and the source of information used to determine map location will also be provided. Recipient also agrees to submit all data relevant to the establishment of paternity at the time such determinations are made.

14. Costs/No Warranties. Recipient agrees to pay a fee to the LLFS of $____ per sample of 10-100 nanograms of DNA to cover actual costs incurred by the LLFS in connection with this request. Costs are subject to change following written notification from the LLFS. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE BIOLOGICAL MATERIALS, GENETIC ANALYSIS DATA, AND CLINICAL DATA PROVIDED TO RECIPIENT UNDER THIS AGREEMENT, OR THAT THE BIOLOGICAL MATERIALS, GENETIC ANALYSIS DATA, OR CLINICAL DATA MAY BE EXPLOITED WITHOUT INFRINGING THE INTELLECTUAL PROPERTY OR PROPRIETARY RIGHTS OF ANY THIRD PARTIES.

15. Recipient's Responsibility for Handling Biological Materials. Recipient acknowledges that Biological Material has the potential for carrying viruses, latent viral genomes, and other infectious agents in an unapparent state. The Recipient agrees to treat Biological Material as if it were not free of contamination, and that Biological Material will be handled by trained persons under laboratory conditions that afford adequate biohazard containment. By accepting Biological Material, Recipient assumes full responsibility for its safe and appropriate handling.

16. Non-Endorsement, Indemnification. Recipient agrees not to claim, infer, or imply Governmental endorsement of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s) except as described in paragraph 7. To the extent permitted by law, Recipient agrees to hold the LLFS, the United States Government, and all other investigator(s) who generated Genetic Analysis Data, and the agents and employees of each of them, harmless and to defend and indemnify all such parties for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose of Clinical Data, Genetic Analysis Data, and Biological Material, its byproducts, or modified or unmodified derivatives.

17. Accuracy of Data. Recipient agrees that the LLFS, the United States Government, and the other investigator(s) who generated Genetic Analysis Data, are not responsible for the accuracy of Genetic Analysis Data provided by other Recipients. The LLFS and the United States Government are not responsible for the accuracy of Clinical Data or Biological Materials provided.

18. Recipient's Compliance with IRB Requirements. Recipient acknowledges that the conditions for use of these Clinical Data and Biological Material have been approved by the Recipient's Institutional Review Board (IRB) in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. Recipient agrees to comply fully with all such conditions and with the subjects" informed consent documents, on record with the LLFS. It is intended that the Recipient's agreements herein shall inure to the benefit of the research subjects, as well as to the parties to this agreement. Recipient agrees to report promptly to the LLFS any proposed change in the research project and any unanticipated problems involving risks to subjects or others. Recipient remains subject to applicable State and local laws and regulations and institutional policies which provide additional protections for human subjects.

19. Conflict of Interest. The Recipient agrees to promptly disclose direct and indirect conflicts of interest, such as affiliation(s) with any organization with an explicit or indirect financial interest in the subject matter of the proposed research employing Clinical Data or Biologic Materials from the LLFS. Examples of such affiliations are employment consultancies, expert testimony, honoraria, stock, or retainers that may affect the work being considered.

20. Amendments. Amendments to this Distribution Agreement must be made in writing and signed by authorized representatives of both parties.

21. Termination. The LLFS may terminate this Distribution Agreement if Recipient is in default of any condition of this Distribution Agreement and such default has not been remedied within 30 days after the date of written notice by the LLFS of such default. Upon termination of this Distribution Agreement, Recipient agrees to return all unused Biological Materials and Clinical Data to the LLFS.

22. Disqualification, Enforcement. Failure to comply with any of the terms specified herein may result in disqualification of Recipient from receiving additional Clinical Data, Biological Materials, and/or Genetic Analysis Data. The LLFS shall have the right to institute and prosecute any proceeding at law or in equity against the Recipient for violating or threatening to violate the confidentiality requirements of this agreement, the limitations on the use of the data or materials provided, or both. Proceedings may be initiated against the violating party, legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding in law or equity, including obtaining the proceeds from any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of this agreement. In addition, Recipient acknowledges and agrees that a breach or threatened breach of the confidentiality requirements or use limitations of this agreement may subject Recipient to legal action on the part of LLFS participants and their families, or the universities participating in the LLFS.

23. Accurate Representations. Recipient expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate.

24. Prior Distribution Agreements. The following two paragraphs apply only to Recipients that have entered into a previous Distribution Agreement:

    a. Execution of this Distribution Agreement is contingent upon Recipient's compliance with all terms and conditions of existing Distribution Agreements with NIA, excluding the requirements stated in paragraph 4 of the previous Distribution Agreement.

    b. If Recipient has executed a previous Distribution Agreement, Recipient agrees to provide the LLFS with a report every twelve (12) months during the term of such prior Distribution Agreement containing Genetic Analysis Data derived by Recipient from any Clinical Data and Biological Materials previously received from the LLFS. Such report will cover all Genetic Analysis Data derived by Recipient up to six (6) months before the reporting date. Recipient agrees that the LLFS may distribute these data to qualified scientific investigators requesting access through established NIA procedures and completing a signed Distribution Agreement comparable to this Agreement. If the effective date of such previous Distribution Agreement was more than twelve (12) months before the time of the current request for Clinical Data and Biological Materials, and Recipient has not provided to the LLFS Genetic Analysis Data derived from any Clinical Data and Biological Materials previously received from the LLFS, Recipient agrees that provision to the LLFS of such Genetic Analysis Data is a precondition for consideration of the current Distribution Agreement.

This Distribution Agreement is entered into as of:

_____ (effective date)

RECIPIENT:

Name of Recipient Entity:

_____

Name and Title of Recipient's Authorized Representative:

Signature and Date of Recipient's Authorized Representative:

PRINCIPAL INVESTIGATOR:

Principal Investigator's Name and Title:

Principal Investigator's Surface Mail Address:

Principal Investigator's E-Mail Address:

Principal Investigator's Telephone Number:

Principal Investigator's Fax Number:

Signature and Date: Principal Investigator:

LLFS:

Name and Title of LLFS Authorized Representative:

Signature and Date of LLFS Authorized Representative:

TRUSTEES OF [ ] UNIVERSITY:

Name and Title of [ ] University's Authorized Representative:

Signature and Date of [ ] University's Authorized Representative:

Signature and Date of Authorized NIA Representative