CHAPTER 26
STUDY ORGANIZATION AND POLICIES

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26.1. STUDY ORGANIZATION

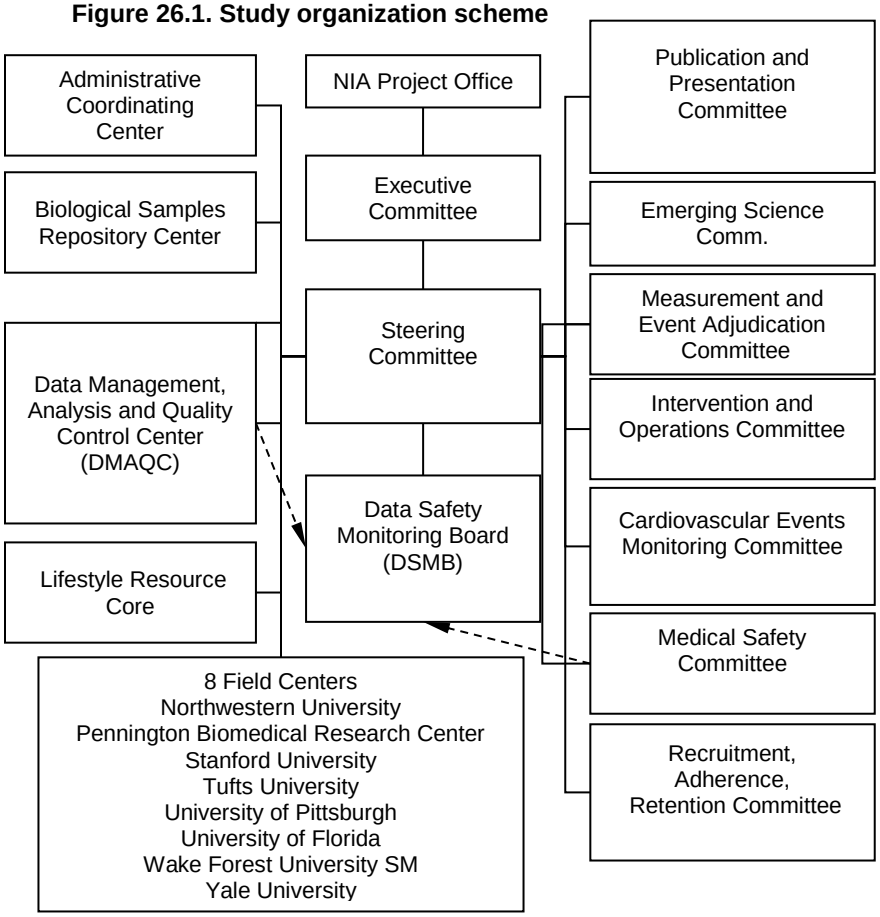
The LIFE study is a cooperative agreement linking eight clinical centers, an Administrative Coordinating Center, collaborating investigators at additional institutions, a data management and quality control center, a biological samples repository center, a lifestyle resource center, and a National Institute on Aging (NIA) project office. The protocol (Chapter 1; Section 10) defines the roles of each of these entities.

The study committees are responsible for the overall administration of the trial. Foremost of these is the LIFE Steering Committee, which consists of the Principal Investigators of each clinical center; the Principal Investigators of the administrative, data management and quality control coordinating centers, additional investigators from other institutions, and the Project Officer from the NIA. In general, motions to the Steering Committee are carried with majority vote. An Executive Committee comprised of the Study Chair and Co-Chair, the Principal Investigator of the coordinating center, one field center PI, and the NIA Project Officer is convened to effect management decisions required between Steering Committee meetings, as needed, for efficient progress of the trial. The Steering Committee and Executive Committee develop standing and *ad hoc* committees and working groups to perform special study tasks and make recommendations to the Steering Committee. Membership on these committees is controlled by the Steering Committee. Committee membership and charges are listed on the LIFE website (see Chapter 27). Notices of committee meetings, meeting agendas, materials for meetings, and minutes from past minutes are also posted on the website. LIFE study personnel are encouraged to communicate directly with committees using e-mail list servers available on the website.

26.1.1 Study Committees

Several center, cores and committees support key components of the study and ensure its successful conduct and completion. (See Figure 26.1) For a complete description of each committee, please refer to Chapter 1-Study Protocol.

Figure 26.1. Study organization scheme



26. 2 P & P POLICY

The LIFE Steering Committee has developed the following policy document for guiding the important task of disseminating study results and defining ownership of study data.

26.2.1. SUMMARY

26.2.1.1. Charge to the Publications and Presentations (P & P) Committee

This committee proposes policy for presenting and publishing LIFE data, including writing group membership, authorship, presentations, data access, and internal manuscript reviews. It coordinates the LIFE publication process to ensure that study results are disseminated in a timely, accurate, and clear manner. The committee routinely reviews the progress of LIFE publications and presentations. It oversees the development of the LIFE slide library and proposes policy regarding its use.

26.2.1.2. Goals

The goals of the LIFE P & P Committee are to:

- ensure accurate, uniform, timely, and high quality reporting of LIFE

activities and results (reporting may be in the form of press releases, interviews, presentations, publications, and the LIFE web site)
- preserve the scientific integrity of the study
- safeguard the rights and confidentiality of participants
- ensure that the timing of P & P serves the right of the public to know the results of the trial without jeopardizing its conduct
- maintain an up-to-date list of LIFE presentations and publications available on the LIFE web site

26.2.1.3. Committee Role in Scientific Publications

The P & P Committee organizes a writing group for each scientific publication or presentation proposed by the members of the LIFE Research Group. Members of writing groups include volunteers from the members of the LIFE Research Group at large, and are not restricted to members of the P & P Committee. The P & P Committee coordinates the efforts of the writing group, establish priorities for data analysis by the coordinating center, and perform an internal review of manuscripts prior to submission for publication. A DMAQC representative also reviews all manuscripts prior to submission in order to verify accuracy and consistency with other LIFE documents and publications. All publications and presentations should give credit to the funding agency by including the following statement “The research upon which this publication is based was performed pursuant to NIA grant U01-AG022376”.

26.2.1.4. Rationale for Authorship Rules

There are several categories of scientific publications and presentations, with different rules for authorship, ranging from publications of the main results of the study (with 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 LIFE Research Group and staff with the need to recognize individuals for specific contributions to certain types of publications and presentations.

26.2.1.5 Duties of the P & P Committee

The duties of the P & P Committee are listed below and concern all scientific and public communications for the LIFE trial, including ancillary studies to the LIFE trial.

- Recommend to the LIFE Steering Committee policy and procedures for review and approval of all scientific and public communications regarding LIFE to outside groups.
- Identify topics for scientific publication and review proposals for LIFE-related publications or presentations.
- Propose policy guidelines for authorship of LIFE scientific publications and appoint writing groups.
- Monitor the progress of writing of each scientific paper to ensure publication in a timely fashion.
- Oversee the review of all LIFE P & P prior to submission.

- Suggest appropriate journals for LIFE publications and monitor the process of publication.
    - Perform other writing, reviewing, or editing tasks assigned by the Steering Committee, including review of public communications in the form of press releases.

26.3. DEFINITIONS OF TYPES OF COMMUNICATIONS

Communications from LIFE may be classified as a web site posting, presentation (includes poster and accompanying abstract), or publication. All of these communications must be reviewed and approved by the P & P Committee, or in some cases specified below—by the P & P Co-Chairs before release or submission.

26.3.1. PRESS RELEASES AND INTERVIEWS

A press release is defined as a document containing LIFE 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. Press releases and interviews regarding material that has already been approved by the Administrative Coordinating Center for previous use does not have to be approved for each subsequent use.

26.3.2. Web Site Posting

LIFE maintains a web site that is available only to LIFE staff members and facilitates communication among members. Any publications to other web sites must follow the same rules as other LIFE publications.

26.3.3. Presentations

A presentation is defined as the delivery of unpublished LIFE 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 Co-chairs must approve all abstracts prior to submission. Proposed abstracts should be submitted to the Co-Chairs at least one week prior to the due date, in order to allow time for review. The Co-Chairs obtain a review from the DMAQC to insure data accuracy, and may obtain reviews from other investigators if they deem it necessary. Approved abstracts are periodically circulated among the LIFE PIs for information purposes. If the abstract is accepted for presentation, the P&P Committee is to be notified promptly by the investigator who submitted the abstract. Copies of slides to be used should, except under unusual circumstances, be submitted to the P & P Co-Chairs prior to the presentation, preferably as an electronic file. Slide files for all LIFE abstracts are maintained on the LIFE website that are available to all LIFE investigators. It is permissible to

submit previously cleared abstracts to other meetings; copies should be sent to the Administrative Coordinating Center for inclusion in the listings of P & P.

26.3.4. 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 or any popular periodical with national circulation.

26.4. Scope of Responsibility for the Publication Policy

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

Individuals, 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, LIFE 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.

26.5. 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:

26.5.1. Category A

Publication of LIFE results deemed “core” publications have no named authors. Author designation is “LIFE Research Group.” An appendix to the publication lists members of the study group and indicate members of the paper’s writing group, other committee membership, and other aspects of contribution to LIFE (see Sections 25.5.6 and 25.6.4). Few, if any, “core” publications are expected from the current LIFE study.

26.5.2. Category B

Other publications using data gathered by all LIFE members are written by designated writing groups whose members are named as authors. The selection and duties of writing groups are described in Section 26.6.4. 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 LIFE Research Group." For all Category B papers, an appendix lists members of the study group. The appendix could be one previously published that is referenced.

26.5.3. Category C

Sub-studies to LIFE may have as their main thrust the analysis of data that were gathered by only a portion of LIFE clinical sites or the analysis of data gathered from a subsample of volunteers from all clinical sites. 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 LIFE Investigators, when appropriate. The named authors are the writing group members (designation and duties described in Section 25.6.4) for the publication. Authors are listed in the following style: "G.H., I.J., K.L. and the DEXA Subgroup of the LIFE Research Group." An appendix lists all members of these smaller groups. If a study has been previously published by this subgroup, reference could be made to a previously published subgroup member's list; and also could reference an earlier paper from the overall LIFE study. Substudies describing a subsample from all clinical sites are considered Category B.

Manuscripts from ancillary studies that require LIFE data from all clinical sites are published as Category B. For ancillary studies to LIFE 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 LIFE investigators, where appropriate. The named authors are in the following style: "M.N., O.P., Q.R. and the Toxicology Subgroup of the LIFE Research Group." An appendix lists all members of these smaller groups. References to a previously published listing of the subgroup membership and to the overall LIFE study suffice.

26.5.4. Other LIFE Personnel as Authors

The writing group for a LIFE manuscript may include trainees, study coordinators, and other LIFE 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. In addition, other academic colleagues who can offer input or important contributions to papers may be invited to participate by the P & P committee.

26.5.5. 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 the person making the presentation),

to be listed as: A.B. Smith, C.D. Garcia, E.F. Johnson, and the LIFE Research Group. A full list of members of the LIFE Research Group is not included.

Responsibility for the category assignment for all publications and presentations rests with the P & P Committee.

26.5.6. Designation of LIFE Members in Appendices of Publications

At the end of Category A and B papers and perhaps for Category C papers, an appendix is included to recognize LIFE Research Group members and their contribution to the study. All professional members of the LIFE Research Group who have the approval of the Principal Investigators and have served at least two years in a significant capacity with the study are listed and are considered as authors. In addition, a Principal Investigator may provide justification in writing to the P & P Committee to include individuals who have been with the study for less than two years for inclusion. This appendix also designates the membership on the paper's writing group (for Category A publications), LIFE committee membership, and roles in LIFE.

Every clinical site and all collaborating entities are listed as participating centers. Those scientific, federal, or commercial organizations providing funding are also recognized.

The published appendix documenting LIFE contributors should be referenced by sub-studies and ancillary studies that use data developed from all clinical sites. A similar appendix acknowledging contributors to the substudy research group and the ancillary research group is developed for Category C publications. In that instance the same format for the Appendix is followed.

26.6. POLICIES AND PROCEDURES

The P & P Committee must approve (by majority vote) all publications.

Some of the communications generated by LIFE promotes trial activities rather than present trial data. During the early period of the trial, it is anticipated that there will be a number of presentations made at national scientific symposia describing the design and methods for LIFE. There will also be presentations describing the recruitment effort and results for the trial. Approval for these presentations is made by the P & P Committee.

The review of a proposed presentation by the Publications Committee shall consider scientific, programmatic, and stylistic aspects of the presentation or abstract, but does not consider the costs of making the presentation. Approval of an abstract or presentation by the P & P Committee implies no commitment of LIFE funds to support the presentation. The head of the writing group proposing an abstract or agreeing to the Committee's request to head a writing group is responsible for obtaining necessary funds for travel, meeting registration, and other costs of making the presentation.

Proposals for presentations and publications, especially those in categories B and C, should be made to the P & P Committee from the members of the LIFE Research Group at large, and thus the P & P Committee does not have the sole responsibility for bringing forward proposals.

The P & P Committee, through the Administrative Coordinating Center, tracks and keeps the Steering Committee informed of the status of all communications, from their inception through review and the final presentation or publication. All communications from LIFE, including those of ancillary studies, are prepared under the oversight of the P & P Committee. Approval may be withheld for publications or presentations of ancillary studies that may jeopardize the outcome of LIFE, until such time as is deemed appropriate by the P & P Committee. Further description follows below.

26.6.1. PRESS RELEASES AND INTERVIEWS

Press releases and interviews used for general publicity and national recruitment launches are initiated by the Recruitment and Retention committee. Centrally prepared press releases are reviewed by the Administrative Coordinating Center and distributed to the centers. It is suggested that these prepared releases be given to the media when interviews are requested. This procedure helps ensure uniformity and accuracy in the information disseminated through the media. Approval by Administrative Coordinating Center is not required for local releases related to recruitment. When local recruiting results in editorial space, providing the clinical site uses the central press release material and the master materials set, approval by Administrative Coordinating Center is not required for local media contact.

Should a clinical center be solicited for information other than that detailed in the master materials set or centrally prepared press releases, the clinical center should refer the soliciting party to Administrative Coordinating Center.

A press release or interview may be appropriate with a presentation or publication announcing a study result of great public interest. Such a press release or interview is approved in advance by the Administrative Coordinating Center and the presentation or publication must be approved as specified below.

Prior approval from the Administrative Coordinating is required for articles targeting the lay press. These articles should be submitted to the Administrative Coordinating Center at LIFEACC@aging.ufl.edu to allow at least seven days for this review.

26.6.2. Presentations

Any LIFE presentation involving previously unpublished data and any presentation to a national or international meeting requires P & P Committee review as described in Section 26.6.2.1 and below. It is the intention of the P & P Committee to approve a master slide set and master materials set (to include

RFA, final LIFE Protocol, and Manual of Operations), which may be used for presentations without content approval by the P & P Committee. These materials are available on the LIFE web site.

A presentation utilizing the master materials set to a regional or local meeting may be given without prior review and approval of the P & P Committee. The presenter should send information about the presentation, including the date, location, audience and an outline or description of topics to be covered to the P & P Co-Chairs and the Administrative Coordinating Center. "Regional or local" refers to the scope of influence of the meeting, not to the location relative to the workplace of the presenter; i.e., a local meeting can take place at a great distance from the workplace of the presenter.

Any LIFE presentation involving previously unpublished data and any presentation to a national or international meeting, regardless of content, must be reviewed as follows:

26.6.2.1. Invited Presentations

If a member of LIFE is personally invited to present LIFE information or represent LIFE at a national or international meeting, the invitation must be forwarded to the P & P Co-Chairs as soon as possible. The P & P Committee reserves the right to accept or decline the invitation and suggest a presenter other than the invited LIFE member in order to distribute the opportunities for presentation widely among the members of the LIFE Research Group.

26.6.2.2. Submitted Presentations

The P & P Committee or LIFE study members at large may suggest meetings and topics for presentation of LIFE material. The P & P Committee identifies (or approves) one person (not necessarily a P & P Committee member) to assume responsibility for assembling a group to prepare and present the material. If several LIFE investigators submit proposals for similar presentations, the P & P Committee requests the involved persons to resolve their differences, and if appropriate, join in a common presentation group. The P & P Committee has responsibility for approving lead author/presenter.

26.6.3. Review of Submitted or Invited Presentations of Unpublished Research Results

The P & P Committee must approve all abstracts of proposed presentations of new data from LIFE. The P & P Committee Co-Chairs must receive abstracts at least one week prior to the submission deadline in order to allow time for review and response to authors. As a courtesy, a copy of each proposed abstract is also circulated to the P & P Committee prior to its submission.

The P & P Committee may ask for revision or clarification of abstracts before approval.

In the event of disagreement between investigators on an abstract submission, the P & P Committee serves as mediator. If an agreement cannot be reached, the LIFE Steering Committee is the final arbiter.

Ordinarily, a LIFE presentation should not be accompanied by a manuscript or other written material, except for an abstract. If a manuscript is requested in conjunction with a presentation (e.g., a "proceedings" paper), such manuscript must be prepared and approved according to the rules and procedures for publications. Approval of the presentation does not constitute approval of the publication. The presenter may or may not be the lead author. The member of the LIFE Research Group accepting an invitation to present LIFE material must make the inviting organization aware of these requirements.

26.6.4. Publications

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

26.6.4.1. Writing Group

When developing an analysis proposal for review by the LIFE P&P Committee it is recommended that first authors seek writing group member feedback before the initial submission to the LIFE P&P webpage. This may be done in a couple of ways. First, if you have specific LIFE investigators in mind, you may contact them directly to be a part of your group, making sure to copy the PI of the site they are affiliated with as a courtesy. Second, you may wish to send an email to all LIFE site PI's to request their nominations to your proposal writing group. Make sure to provide an outline or draft of your proposal so that the site PI has an idea of the area you are seeking to research. Last, you may ask the LIFE-ACC to contact site PI's on your behalf to request nominations. This process will help to ensure that there is representation from each LIFE field center on every proposal and allow more opportunities for review and feedback before it goes to the full P&P Committee for a vote. When contacting LIFE site PI's, authors should allow one week for writing group nominees to provide feedback. At the end of the week a follow-up email should be sent to give nominees an additional week to respond. Two weeks after the initial email, authors can notify LIFE-ACC and the proposal will be forwarded to DMAQC and the P&P review process will begin. Please remember the following when contacting LIFE site PI's for nominations:

1. Always include the DMAQC PI.
2. For all LIFE-Main trial analyses, all LIFE sites must be afforded the opportunity to nominate a representative. Please contact LIFE-ACC if you are unsure of which sites to contact.
3. For all LIFE-Pilot analyses, only sites that were part of the pilot study are required to be contacted for representatives.
4. Ancillary studies only require representation from the sites where new data is being collected.

Guidelines for completing the proposal form are available on the LIFE website. The writing group proposal identifies the writing group chair, other potential writing-group members, provides a brief background for the proposal and specifies the research question/topic to be addressed, identifies the LIFE data to be used in the analysis. Proposals will be loaded through the LIFE web-site. Prior to review, a DMAQC statistician will be assigned to the analysis plan and work with the writing group chair to refine the analysis approach and nominate a DMAQC representative to the writing group. After this consultation a finalized analysis proposal is uploaded. The P&P Committee reviews the final analysis plan for scientific content and approves the writing group composition. The committee can approve proposals, reject proposals or ask for revisions. Writing groups consist of at least three individuals for each proposed publication. Members of the writing group are drawn from the members of the LIFE Research Group at large. In some instances, an individual member of the LIFE Research Group volunteers to develop a manuscript. In other instances, the P & P Committee develops the idea and description of the paper as well as nominated members of the writing group for a proposed paper. Members of the LIFE Research Group may request to join the writing team and are included to the extent practical. For papers involving analysis of data, at least one member of the writing group is from the DMAQC center. Broad participation is encouraged. Equitable distribution of papers among participating centers is the goal of the P & P Committee. For ancillary studies involving a subset of clinical sites, not more than four members of the writing group should hail from one clinical site. The number of members of the writing group is subject to the rules limiting the number of authors for the journal targeted for submission. The P & P Committee approves (by majority vote) the final constitution of the writing group and approves one individual as chair 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 DMAQC, the P & P Committee, and the target journal editors.
- Prepare outlines.
- Request data analyses from DMAQC.
- 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, subject to final approval by P & P Committee.
- Prepare and send semi-annual progress reports to P & P Committee.
- 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 final peer-reviewed manuscripts to PubMed Central within **12 months of publication** in accordance with the NIH Public Access Policy. (For instructions go to: http://publicaccess.nih.gov/)
- Submit reprint of published article to the LIFE Administrative Coordinating Center.

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.

[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 LIFE Investigator committed to fulfilling these functions.

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

26.6.4.2. Writing Group Leader

Once an investigator accepts responsibility as writing group leader, he/she 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. The P & P Committee informs the Steering Committee of the planned publication, including the topic, journal(s) identified for submission, and members and Chairperson of the writing group. Any member of the LIFE Research Group may appeal to the Co-Chairs of the P & P Committee about these matters or about a potential conflict with other proposals for publication. In the event of disagreement, the P & P Committee is the final arbiter, although decisions may be appealed to the Steering Committee. 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.

An investigator may not lead more than two active writing groups at the same

time. Active writing group leadership begins when an analysis plan is submitted to the P&P for approval and ends when the approved manuscript is submitted to a journal for review.

A writing group leader may withdraw a previously approved proposal after discussion with the writing group and the P&P chairs. A writing group leader can request that writing group leadership be transferred to another writing group member by submitting a request to the P&P committee indicating the assent of the writing group and the agreement of the new leader. Written communication from the intended new leader agreeing to the transfer should also be submitted to the P&P committee.

26.6.4.3. Journal Identification

The P & P Committee suggests (or endorse the recommendation of the writing group) an appropriate journal for the submission of each proposed publication.

26.6.4.4. Preparation

The P & P Committee monitors the progress of papers. Some papers are followed as “urgent” if publication is essential for the success of the study or for the publication of subsequent papers. The P & P Committee shall have the authority and responsibility to rank the priority of papers for data analysis by the coordinating center.

26.6.4.5. Initial Manuscript Review

The P & P Committee members receive the paper for initial review and also sends the manuscript to a DMAQC center investigator for verification of data and analyses. After these reviews are completed they will be circulated to the full P & P committee for approval. Manuscripts from ancillary studies may require verification of data analyses by the LIFE coordinating center. To facilitate this, documented data underlying these manuscripts must be transferred to the coordinating center prior to its review.

26.6.4.6. Approval for Category A and B Manuscripts

Following review, the manuscript of a Category A or B publication must be approved by a majority of the P & P Committee. It then may be submitted to the journal by the primary author. The leader of the writing group usually serves as corresponding author.

26.6.4.7. 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.

26.6.4.8. Page and Reprint Charges

The Administrative Coordinating Center funds any page and reprint charges for manuscripts. Advance approval of such expenditures must be obtained from the PI of the Administrative Coordinating Center. Page and reprint charges for ancillary studies must be funded separately.

26.6.4.9 Use of LIFE Data for Theses by Graduate Students

All requests for use of LIFE data by students are to be reviewed by the P & P Committee. It is required that the student requesting use for LIFE data is associated with the study through the LIFE investigator who is acting as the student's "sponsor" with regard to the data. LIFE data may not be used by students if the data relate to major LIFE 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) a statement acknowledging LIFE for use of the data, and b) statement indicating that opinions, ideas, and interpretations included in the thesis are those of the student alone and not those of the LIFE investigators.

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 LIFE PI "sponsor" to ensure that the thesis accurately reflects the conduct and data from LIFE, as dissertations are technically available to the public without having gone through the P & P review process. The standard LIFE publication policy is to apply to any material published from the thesis. LIFE 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.

26.6.4.10 Use of LIFE Data for Grant Application or Contract Proposal

LIFE 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 LIFE Steering Committee.

26.7. INTERIM ANALYSES, TIMELINE FOR PUBLICATION AND DATA REPORTS TO STEERING COMMITTEE

26.7.1. Rationale for Interim Analyses

There currently are no planned interim analyses relative to early stopping guidelines for The LIFE Study. Interim summaries of safety, efficacy, and performance are presented to the Data Safety and Monitoring Board (DSMB) on

a regular basis, and recommendations of the DSMB and Steering Committee will be followed.

26.7.2. Anticipated Timeline for Publication

Initially, several publications may emanate from The LIFE describing the process of developing the study. Then, after all participants have been enrolled, publications may describe the baseline characteristics of the participants. It is anticipated that there will be no publication of follow-up data prior to completion of the study. No measurements involved in the determination of the primary endpoint or closely related to the primary endpoint are released for publication at any time prior to completion of the final follow-up, unless dictated by the DSMB and Steering Committee.

26.7.3. Reports of Data to the Steering Committee

During the course of the LIFE Study trial, it is be necessary to present data analysis reports for some measures by intervention group (Lifestyle Intervention and/or Community Care) to the LIFE Study Steering Committee. The categories below describe the release of data to the Steering Committee.

26.7.3.1. Data Presented by Intervention Group

Baseline characteristics of each intervention group are presented to the Steering Committee in order to assess the overall performance of the randomization algorithm. Markers of intervention delivery may be presented by intervention group, only if a strong case can be made that this is truly necessary to achieve a balanced approach between intervention groups. These reports are made to the Steering Committee at regular intervals throughout the period of active intervention. In no instances are there releases of measurements used to determine the primary endpoint by intervention group prior to the end of the study.

26.7.3.2. Data Presented only in Aggregate

The Steering Committee receives reports of adverse events in order to compare rates among sites and discuss safety. Pooled data are used to describe participant retention and other quality control benchmarks.

26.8. STANDARDS OF EXCELLENCE

In addition to the review system established for the critique of P & P as described in the previous Section, the following guidelines are suggested for maintaining the highest standards of excellence for LIFE P & P.

If, in the opinion of the members of the P & P Committee, no member of the LIFE Research Group has sufficient scientific background to review the pertinent material, outside (of LIFE) expert consultants are be selected by the P & P Committee and asked to critique the material.

For the major publications and presentations, the completeness and adequacy of

the reports are assured by consideration of the steps described in "A Proposal for Structured Reporting of Randomized Controlled Trials", JAMA 1994; 272:1926-1931 and subsequent publications by CONSORT. While these considerations should govern the design and conduct of the trial, not all points need to be mentioned in each publication or presentation.

26.9. GRIEVANCES

A member of the LIFE Research Group may formally appeal, in the case of disagreement with the P & P Committee, concerning: 1) the classification of a communication, 2) the membership or chairmanship of a writing or presentation group, 3) the handling or approval of a communication, 4) authorship order, 5) the suitability of a presentation or publication, or 6) any other action taken by the P & P Committee.

To initiate an appeal, the claimant should initially discuss the issue with the Co-Chairs 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 Administrative Coordinating Center for distribution to the entire P & P Committee. The P & P Committee reviews the grievance and responds in writing within four weeks of receipt of the appeal. A decision of the P & P Committee regarding a grievance is binding, but the decision may be appealed to the Steering Committee.

26.10. 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 randomized in LIFE. Subjects evaluated for eligibility but not randomized (for whatever reason) are eligible for other studies. Any data obtained during the screening and eligibility process of LIFE, 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.

LIFE study data are owned jointly by the individual clinical centers, the NIA, the Administrative Coordinating Center, biological samples repository center, and the DMAQC center, but kept at the DMAQC. 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 Steering Committee.

For approved ancillary studies and sub-studies, the LIFE DMAQC center 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 Steering Committee may be released. No data on the primary outcome are released, for example, until the end of LIFE. The time points for data release must also be approved by the Steering 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 termination of the ancillary study. Ownership of data is thus shared by the ancillary study center and the coordinating center.

When the coordinating center ceases to function as an analytic resource to LIFE (i.e., funding terminates), it releases a fully documented copy of all LIFE data to each clinical center and the NIH. Two years subsequent to this release, the full data set are made public. Decisions regarding disclosure of data to other parties, such as pharmaceutical companies or the FDA (beyond the required reports), shall be determined by the Steering Committee. Confidentiality of individual participants is be maintained with all releases of data.

26.11. PRESENTATIONS TO VOLUNTEER PARTICIPANTS

The volunteer participants in LIFE are offered all key results (e.g. effects of treatments on the primary outcome or other important results) prior to presentations to the public or to the professional communities. For the primary outcome results, this should be done by oral presentations to participants at each clinical center, accompanied by a written report to those unable to attend the oral presentation.

26.12. INDUSTRY POLICY

The LIFE 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 LIFE personnel without first receiving clearance from the LIFE Executive Committee.

26.13. ANCILLARY STUDIES POLICY

LIFE Ancillary Study Policy

The LIFE Steering and Emerging Science Committees encourage the development of ancillary studies that enhance the scientific output of the LIFE study. Such studies should: 1) explore the mechanisms of the benefits of exercise, 2) identify improvement in prediction of adherence or response to the intervention, or 3) expand on the assessment of secondary and tertiary outcomes.

An ancillary study is defined as an investigation which is not part of the central, NIA-funded LIFE protocol but uses LIFE participants, samples, or data collected by LIFE. In most cases, an ancillary study involves acquisition of additional data which are not compiled as part of the core LIFE data set. Support for ancillary studies is derived from sources other than LIFE cooperative agreement funds. Examples include studies funded by investigator-initiated NIH research awards (R01, R21, etc), grants from academic institutions, private sources (e.g. drug

companies or foundations), or those performed at no cost to LIFE (generally because of the special interest and resources of an investigator).

Pilot studies involving existing LIFE resources that do not involve specific research hypotheses and for which analyses results will only be used as preliminary data for LIFE related grant submissions do not require formal review by the Emerging Science committee. The LIFE Study Principal Investigator must approve these analyses and the Emerging Science committee will be informed of pilot studies that are being performed under this policy. Results of the completed pilot study analyses will be forwarded to DMAQC and the chair and co-chair of the P and P committee.

Investigators are encouraged to propose and conduct ancillary studies. Such studies enhance the value of LIFE and ensure the continued interest of the diverse group of investigators who are critical to the success of the study as a whole.

Before submitting an ancillary study proposal, investigators should evaluate for potential overlap with an approved, active, or completed ancillary study. A table of ancillary studies will be made available on the LIFE website (https://www.thelifestudy.org). If there is any overlap or similarity with an existing ancillary study, investigators should contact the PI of the study to determine whether revisions to the proposal are necessary. The investigator will then provide information about the communication with the PI(s) of the previously approved study(s) and provide information regarding how the current proposal is sufficiently distinct from previously approved studies. A LIFE-ACC staff person will also conduct a review of current LIFE ancillary studies to help prevent overlapping proposals.

Monitoring Burden

The primary data collection for the LIFE study will have priority over ancillary studies. All baseline data must be collected prior to ancillary study data at the baseline visits. Information about potential ancillary studies will be provided at the initial screening visit, and actual enrollment with consent after baseline data collection is complete but prior to the first intervention visit after randomization. Participation in multiple ancillary studies will be permitted as long as this does not affect participation in the main trial.

Participants should be informed at their first screening visit of the potential ancillary studies that they can participate in at their study site. However, actual recruitment and enrollment in any ancillary studies (excluding lateral mobility and DEXA) should not occur until after baseline data collection is completed. Participation in multiple ancillary studies is allowable, but not at the risk of over burden. As a guideline to reduce burden, the maximum number of additional measurements per participant will be limited to three per visit. To minimize

burden of time, ancillary study measures should be scheduled, if possible, in conjunction with a scheduled study visit (e.g., their initial face-to-face meeting with the interventionist). The DMAQC will be responsible for tracking ancillary study enrollment through the central database. Locally, information on ancillary study participation will be filed on the chart and a local log will also be maintained to track added ancillary study measurement for each study visit including each follow-up visit.

A case-management approach will be employed to monitor follow-up burden. Study staff will be responsible for monitoring burden, fatigue and perception of the intervention and reporting any issues to the ES committee. The study follow-up information will take priority and must be obtained before ancillary study follow-up data are obtained. If there is a clear manifestation of excess burden, ancillary studies will not be completed on those participants. Study coordinators will discuss with participants their level of burden and satisfaction. Participants will have the option not to continue in any or all ancillary studies. If a participant is enrolled in more than one ancillary study, it will be up to them to decide which one they want to continue, if any.

Review Process

To protect the integrity of LIFE, all ancillary studies must be reviewed and approved before access to data or participants is permitted. The review process is as follows:

1. Timeline – For ancillary studies that require added measurements before randomization, the proposal should be submitted two months before grant deadline, following the overall study recruitment timeline.
2. New ancillary study proposals should be sent to the Emerging Science Committee via the Coordinating Center. The Coordinating Center member of the Emerging Science Committee ascertains that the proposal includes adequate information for review. If all required parts of the proposal are included, the proposal is be logged into the Ancillary Study Tracking System and a file is established. If the form is incomplete, the initiator of the proposal is contacted and requested to modify or add the required information. Ancillary Study forms can be found on the study website.
3. The chair and the Administrative Coordinating Center representative for the ancillary studies subcommittee initially screens the ancillary study to determine if issues pertaining to participant burden, blinding and/or blood laboratory use need to be addressed. If the proposal indicates biologic specimen use of any kind, it is sent to the Biologic Samples Repository Committee simultaneously for review. Both committees' evaluations are due within four weeks.

4. Following reviews, the proposal is discussed by the Emerging Science Committee and a recommendation forwarded to the Steering Committee. The comments made by the reviewers are attached to the proposal submitted to the Steering Committee.
5. Initial approval/disapproval is be made by the Emerging Science Committee. The Steering Committee is allowed two weeks to make their decision. If concerns are major, Steering Committee comments are sent back to the initial investigator for response and modification of the proposal if requested by the Steering Committee.
6. Once approved by the Steering Committee, the proposal is sent to the Data Safety Monitoring Board (DSMB) for approval. All ancillary studies must be approved by the DSMB. Any adverse event or clinical disease detected by an ancillary study must also be reported during the course of the ancillary study to the Steering Committee (via the Emerging Science Committee) and to the DSMB. Two weeks are provided for this review.
7. Once all approvals have been granted, letters documenting the approval is sent separately from the chair of the Emerging Science Committee on behalf of the Steering Committee and from the DSMB (depending on type of review).
8. Changes in ancillary studies, such as revised applications, are subject to re-review and approval. If the ancillary study revision does not result in a change in the sample size, participating sites, participant burden, life staff use, biorepository use, or the data coordinating center, the ES committee at their discretion can approve the revised submission with an updated memo that endorses the original letters of approval. If changes in the ancillary study include changes in sample size, participating sites, participant burden, biorepository use, LIFE staff use, or data coordinating center use, then full review and approval at all levels will be required. The Emerging Science Committee will determine this based on a revised application to the Emerging Science Committee that highlights the changes in the application. This should be submitted according to the timeline for new proposals to the ES committee, which is 8 weeks before the grant deadline.
9. Principal investigators of ancillary study proposals should either submit their proposal for funding or begin their study within 2 years of receiving final approval for their ancillary study. If the proposal is submitted for funding, the PI is required to update the Coordinating Center of the review outcome, including approval for funding or disapproval for funding and plans to re-submit the proposal within one month of receiving a priority score. If there is no action by the PI regarding submission for funding or beginning the study within two years after LIFE approval for their ancillary study, then the Emerging Science Committee has the discretion to withdraw the proposal and allow other investigators to pursue similar scientific aims. In addition, the PI will have 90 days to address any concerns raised in the LIFE ancillary study review process. If the PI does not submit a response to feedback within 90 days after receiving

comments, then the ancillary study will be considered “closed” and another investigator will have opportunity to pursue a similar study.

Timing of Ancillary Study Requests

All proposed ancillary studies must be submitted to the Emerging Science Committee in time for review, circulation to appropriate committees, and consideration by the Steering Committee and the DSMB prior to submission to a funding agency. In general, studies requiring review by all parties, i.e. Emerging Science Committee, Biologic Specimens Committee, Steering Committee, and DSMB, require that the proposal be received at the Coordinating Center eight weeks prior to the submission to the funding source. Proposals not requiring DSMB review may be accepted up to six weeks prior to submission. Studies submitted for review in less than these time periods prior to a funding application deadline may not receive approval.

Criteria for Approval

Reviewers assess the priority of the ancillary study in relation to LIFE objectives, and most importantly, determine its potential impact on the main study. Highest priority will be given to studies which:

- Are consistent with the original purpose of the LIFE;
- Are characterized by innovation, novelty and clear scientific design;
- Have a LIFE investigator as a full collaborator, taking responsibility for proper conduct of the study and reporting of data;
- Do not impede the collection of the primary study data.
- Are sufficiently scientifically distinct from previously approved ancillary studies.
- Make a scientific contribution in more than one area at once. In addition, priority for studies requesting blood samples is highest if they:

    - Do not make use of samples from those participants with the fewest samples;
    - Use of small sample volumes; evidence of attempts to minimize volumes are examined by the Biologic Specimens Committee.
    - Can be integrated with other studies to conserve sample or limit freeze-thaw cycles.

The review primarily focuses on whether the burden to the participants and staff is acceptable and if blinding is maintained so that the study does not compromise, complicate or jeopardize the conduct of the LIFE. In most cases, additional data collection should be scheduled to take place after the baseline data has been collected and should include a separate consent form. Review of the proposed ancillary studies for scientific merit is not the primary responsibility

of this review process, but is a necessary consideration for allocation of access to scarce LIFE resources.

Proposal Format

In order to expedite review of ancillary studies, LIFE has developed a proposal form that provides a synopsis of the impact of the study on LIFE. This should be followed by a brief 2-3 page synopsis of the aims, background and methods, including power calculations of the proposed study. The form can be found on the LIFE web page. The proposals form should contain:

PART 1: Basic Study Information and Projected Impact on LIFE

1. Title of study
2. Initiating investigator(s) (name, address, phone and fax numbers, e-mail address)
3. Proposed collaborators
4. Proposed starting and ending dates
5. Source of funding; date of grant submission
6. Summary of overall Impact on the main study
7. Summary of Field Center, Coordinating Center, and DMAQC tasks involved:

Center	Examine participants (N)	Analyze samples (N participants)	Analyze data (yes/no)

8. Description of participant, specimen and staff involvement

A. Participants

1. Burden: Describe number of subjects needed; special characteristics of study population; and age and sex distribution. Will participants be contacted, interviewed, or examined? If so, describe participant involvement and the specific time-point of planned data collection (Note that in most cases additional data should be collected after the main baseline data has been collected). Estimate time/effort required of each participant.

2. Safety monitoring: Will the ancillary study will have its own safety monitoring or will rely on the LIFE DSMB for this? Describe the safety implications of the study and plans for reporting adverse events to LIFE.

3. Masking: Describe how the ancillary study will maintain masking to intervention assignment.

B. Stored materials (- if plans include separate blood draw, state plans for managing specimens):
Describe materials to be used (e.g., blood, urine, other samples).
i. i. From which cohort (LIFE-P or LIFE-M or both) are samples requested?
ii. Provide justification for the cohort(s) selected.
iii. Study year(s) for which samples are to be used (e.g. baseline, follow-up)
iv. Sample type (e.g. serum, EDTA, DNA)
v. Requirement for frozen vs. previously thawed samples
vi. Sample volumes
vii. Efforts to integrate sample needs with those of other studies to conserve sample and/or limit freeze-thaw cycles.

C. Field Centers:
Describe effort (and estimated time) required of staff at each participating center.

D. Data Management and Quality Control Center:
Describe effort (and estimated time) required of DMAQC staff.
Specifically:
i. Will the DMAQC be involved in data collection, tracking, or preparation of forms or software? (Note that if these tasks will be completed by the Ancillary Study, a data file must be sent to the DMAQC. The ancillary consent forms must include permission from participants for this data transfer and for the data to be used in LIFE publications)
ii. Will data analyses be done by analysts at the DMAQC?
iii. iii. Are any subgroup analyses (e.g. by baseline SPPB level) planned? If yes, please specify the subgroup analyses proposed.

E. Assurances:

1. Assurances that data will be provided back to the main study for use by other investigators once the ancillary study objectives have been met or manuscripts have been prepared for publication (see "Other Requirements of an Ancillary Study," below).
2. Assurance that the Ancillary Study PI will report progress of the study from status of funding through data collection and manuscript publication.
3. Blinding, safety monitoring (if appropriate), and confidentiality of individually identifiable LIFE participants must be assured.

4. List the study(s) with overlap/similarity and their principal investigator or indicate if the proposed study does not have any overlap/similarity with previously approved LIFE-Pilot or LIFE-Main ancillary study proposals.
5. If overlap or similarity exists, the principal investigator (PI) of the newly proposed study must describe communication with the approved study's PI. The PI of the newly proposed study must indicate how the currently proposed study is sufficiently distinct from the previously approved related study. The PI should also indicate how any potential overlap would be handled.

PART 2: Description of the Proposed Ancillary Study

Please provide a brief (1-3 page) description of the proposed study. Include the following:

1. Background and rationale
2. Study aims: questions or hypotheses
3. Methods, including:
   Participant involvement (if any)
   Safety monitoring and masking
   Data to be collected
   Data needed from the main study (including outcomes/events)
   Sample size justification
4. Literature references

Other Requirements of an Ancillary Study

1. Studies that will collect new data from participants must obtain a separate informed consent from all ancillary study participants. This consent should clearly identify the ancillary study as one being performed in addition to the main study and inform subjects that their participation in the ancillary study is not necessary for them to continue in LIFE. The informed consent must allow for the transfer of ancillary study to the DMAQC and for its potential use in future LIFE publications, as governed by the LIFE Publications Policy. IRB approval and the informed consent must be provided to the Emerging Science Committee before implementation of the proposed study begins. Documentation of IRB approval is required to be submitted to DMAQC before any LIFE data can be transferred to ancillary study investigators.

2. If an approved proposal involves genetic studies, ethical, legal and social implications, as well as reporting of results, must be proactively addressed in the proposal. Confidentiality of individually identifiable data about LIFE participants

must be assured. LIFE provides no assurances that ancillary studies will be able to identify and contact participants in the future, particularly after LIFE ends.

3. A LIFE investigator is expected to lead or sponsor an ancillary study, either as PI or as a co-investigator. This individual would be responsible for presenting the study to the Emerging Science Committee, to monitor the study to assure continuing compatibility with LIFE and serving as a liaison to the LIFE Steering Committee. In addition, each manuscript and abstract would generally be expected to include a LIFE investigator, except under circumstances that should be stated and rationalized as part of the original submission to the Ancillary Studies Committee (for the review process, see P&P policy outlined below).

4. All LIFE sites designated for inclusion in the study must have agreement from the respective Principal Investigator.

5. Ancillary study data that are requested by the study PI will be distributed by the DMAQC once permission has been granted by the LIFE Steering Committee. Upon completion of analysis, the data will be returned to the DMAQC for the purpose of archiving and for potential use in LIFE publications. Data must be provided electronically with documentation. The effort related to distributing LIFE data to the ancillary study and receiving ancillary study data and merging them with the main database must be covered by the ancillary study funding through a subcontract with DMAQC. The ancillary study PI is given the first and exclusive opportunity to analyze, present and publish data collected under the auspices of the ancillary study. Six months after the ancillary study data are linked with PIDs, the ancillary study data are made available for additional uses by LIFE investigators, in collaboration with the ancillary investigators. It is the responsibility of the ancillary study PI to state in writing to the Steering Committee any special circumstances that would militate against these guidelines for data sharing. In the spirit of encouraging collaboration, reasonable and justified requests for limiting access to the data are honored or some compromise is worked out.

6. No funds from the main LIFE cooperative agreement may be used to support an ancillary study. Thus, it is crucial that subcontracts to the sites, the Coordinating Center, and/or the DMAQC be included in requests for funding which covers all data collection and/or blood laboratory analyses, costs associated with data transfer, and any data analyses.

7. A manuscript proposal must be reviewed and approved by LIFE before submitting an abstract or manuscript regarding the ancillary study. See below.

Publications and Presentations Resulting from Ancillary Studies – To be reviewed and approved first by P and P before forwarding to the SC.

All the publications, presentations and abstracts from an ancillary study must be reviewed and approved by the LIFE Publications and Presentations Subcommittee (P&P) and other review groups (Steering Committee, NIA) prior to submission or presentation, in accordance with the general rules for publications and presentations. (See Publications & Presentations Policy for guidelines). While the P&P does not track these manuscripts in the detail that main study papers are tracked, it is the responsibility of the Ancillary Study PI to make sure that all manuscript proposals, abstracts and final manuscripts and have been submitted for inclusion in the LIFE P&P database, that penultimate drafts are submitted for review, and that details concerning publication status are reported back to the P&P Subcommittee. The following rules apply:

1. For all potential manuscripts, a formal proposal, which consists of a title, proposed Writing Group, introduction, analysis plan, conclusion, and references, must be submitted to P&P.

2. The proposed writing group should include representatives of each site that contributed to the collection of ancillary study data.

3. P&P Committee submits the proposal to the Steering Committee.

4. The P&P Committee also reviews the final draft of any manuscript arising from an ancillary study.

5. If the Penultimate Draft is approved by the P&P Committee, the draft is submitted to the Steering Committee and NIA for final review.

6. The Chairperson of the writing group for the paper is responsible for reporting to the P&P Committee on the paper's progress.

7. The final published article must be sent to the Coordinating Center.

8. Abstracts generated from ancillary studies must follow the same guidelines for all LIFE abstracts (see P&P policy)

Industry-sponsored Ancillary Studies

Proposals for industry-sponsored ancillary studies are evaluated in accordance with the procedures described above. In addition, it is the responsibility of the PI to obtain agreement with the industry sponsor through an appropriate contractual mechanism that all data relevant to the LIFE ancillary study will be shared with the DMAQC and the Steering Committee. Conduct of industry-sponsored ancillary studies also must comply with all existing LIFE and NIH policies and guidelines.

Appendix A – Emerging Science Approval Letter

Date

PI Name and Address

Re: [Ancillary Study Proposal Title]

Dear Dr. XXXXX:

The LIFE Emerging Science Committee reviewed the above-named ancillary study proposal and made a motion to approve the proposal, contingent upon approval by the LIFE Steering Committee and Data Safety and Monitoring Board (DSMB). You will be notified in writing upon final approval. Please note that you are not approved to begin data collection for your ancillary study or apply for external funding until you receive final approval.

The Emerging Science Committee will review all ancillary studies at least annually for progress and productivity and prepare a report for the Steering Committee and the DSMB. Please review your responsibilities for reporting progress and for gaining prior approval for abstracts and manuscripts that are outlined in the LIFE ancillary study policy (www.thelifestudy.org).

Best wishes for a successful ancillary study. We look forward to working with you on the LIFE study.

Regards,
Anne Newman, MD, MPH
Chair, LIFE Emerging Science Committee

Mary McDermott, MD
Co-Chair, LIFE Emerging Science Committee

Appendix B – Emerging Science Provisional Approval Letter

Date

PI Name and Address

RE: Ancillary Study Proposal Title

Dear Dr.XXXXX:

The LIFE Emerging Science Committee reviewed the above-named ancillary study proposal and made a motion to grant provisional approval provided that you address the major comments below. Please forward your response in writing to me by [2-week deadline from date of letter]. Your response will be reviewed and we will contact you when a decision has been reached.

Once approved by our Committee, we will forward the proposal to the Steering Committee and the Data Safety and Monitoring Board. You will be notified in writing upon final approval. Please note that you are not approved to begin data collection for your ancillary study or apply for external funding until you receive final approval.

Regards,
Anne Newman, MD, MPH
Chair, LIFE Emerging Science Committee

Mary McDermott, MD
Co-Chair, LIFE Emerging Science Committee

Appendix C – Emerging Science Revise/Resubmit Letter

Date

PI Name and Address

RE: Ancillary Study Proposal Title

Dear Dr. XXXXX:

The LIFE Emerging Science Committee reviewed the above-named ancillary study proposal and has requested that the proposal be revised and resubmitted based on the comments listed below. Please resubmit the revised proposal by [2-week deadline from date of letter]. Upon review of the revised proposal, you will be contacted in writing regarding the Committee's decision.

Once approved by our Committee, we will forward the proposal to the Steering Committee and the Data Safety and Monitoring Board. You will be notified in writing upon final approval. Please note that you are not approved to begin data collection for your ancillary study or apply for external funding until you receive final approval.

Regards,

Anne Newman, MD, MPH
Chair, LIFE Emerging Science Committee

Mary McDermott, MD
Co-Chair, LIFE Emerging Science Committee

Appendix D – Emerging Science Committee Rejection Letter

Date

PI Name and Address

RE: Ancillary Study Proposal Title

Dear Dr. XXXX:

Thank you for submitting the above-named ancillary study proposal. The LIFE Emerging Science Committee reviewed the proposal and regrets to inform you that it has not been accepted based upon reasons listed below.

Regards,
Anne Newman, MD, MPH
Chair, LIFE Emerging Science Committee

Mary McDermott, MD
Co-Chair, LIFE Emerging Science Committee

Appendix E – Steering Committee Approval Letter

Date

PI Name and Address

Re: [Ancillary Study Proposal Title]

Dear Dr. XXXXX:

The LIFE Steering Committee reviewed the above-named ancillary study proposal and made a motion to approve the proposal, contingent upon approval by the LIFE Data Safety and Monitoring Board (DSMB). You will be notified in writing upon final approval. Please note that you are not approved to begin data collection for your ancillary study or apply for external funding until you receive final approval.

The Emerging Science Committee will review all ancillary studies at least annually for progress and productivity and prepare a report for the Steering Committee and the DSMB. Please review your responsibilities for reporting progress and for gaining prior approval for abstracts and manuscripts that are outlined in the LIFE ancillary study policy (www.thelifestudy.org).

Best wishes for a successful ancillary study. We look forward to working with you on the LIFE study.

Regards,
Anne Newman, MD, MPH
Chair, LIFE Emerging Science Committee

Mary McDermott, MD
Co-Chair, LIFE Emerging Science Committee

Appendix F – Steering Committee Provisional Approval Letter

Date

PI Name and Address

RE: Ancillary Study Proposal Title

Dear Dr. XXXXX:

The LIFE Steering Committee reviewed the above-named ancillary study proposal and made a motion to grant provisional approval provided that you address the major comments below. Please forward your response in writing to me by [2-week deadline from date of letter]. Your response will be reviewed and we will contact you when a decision has been reached.

Once approved by the Steering Committee, we will forward the proposal to the Data Safety and Monitoring Board. You will be notified in writing upon final approval. Please note that you are not approved to begin data collection for your ancillary study or apply for external funding until you receive final approval.

Regards,

Anne Newman, MD, MPH
Chair, LIFE Emerging Science Committee

Mary McDermott, MD
Co-Chair, LIFE Emerging Science Committee

Appendix G – Steering Committee Revise/Resubmit Letter

Date

PI Name and Address

RE: Ancillary Study Proposal Title

Dear Dr. XXXXX:

The LIFE Steering Committee reviewed the above-named ancillary study proposal and has requested that the proposal be revised and resubmitted based on the comments listed below. Please resubmit the revised proposal by [2-week deadline from date of letter]. Upon review of the revised proposal, you will be contacted in writing regarding the Committee's decision.

Once approved by the Steering Committee, we will forward the proposal to the Data Safety and Monitoring Board. You will be notified in writing upon final approval. Please note that you are not approved to begin data collection for your ancillary study or apply for external funding until you receive final approval.

Regards,

Anne Newman, MD, MPH
Chair, LIFE Emerging Science Committee

Mary McDermott, MD
Co-Chair, LIFE Emerging Science Committee

Appendix H – Steering Committee Rejection Letter

Date

PI Name and Address

RE: Ancillary Study Proposal Title

Dear Dr. XXXXX:

Thank you for submitting the above-named ancillary study proposal. The LIFE Steering Committee reviewed the proposal and regrets to inform you that it has not been accepted based upon reasons listed below.

Regards,

Anne Newman, MD, MPH
Chair, LIFE Emerging Science Committee

Mary McDermott, MD
Co-Chair, LIFE Emerging Science Committee

Appendix I – DSMB Approval Letter

Date

PI Name and Address

Re: [Ancillary Study Proposal Title]

Dear Dr. XXXXX:

I am pleased to inform you that the above named ancillary study has been approved by the LIFE Data and Safety Monitoring Board (DSMB). You are now approved to apply for external funding and/or begin data collection for your ancillary study.

The Emerging Science Committee will review all ancillary studies at least annually for progress and productivity and prepare a report for the Steering Committee and the DSMB. If no action is taken to apply for funding or begin data collection by [2 year deadline from date of letter] your study proposal will be officially withdrawn and other investigators will be able to submit similar study proposals. Please review your responsibilities for reporting progress and for gaining prior approval for abstracts and manuscripts that are outlined in the LIFE ancillary study policy (www.thelifestudy.org).

Best wishes for a successful ancillary study.

Regards,

Marco Pahor, MD
Principal Investigator, LIFE Study

Jack Guralnik, MD, PhD
Co-Principal Investigator, LIFE Study

Appendix J – DSMB Provisional Approval Letter

Date

PI Name and Address

RE: Ancillary Study Proposal Title

Dear Dr. XXXXX:

The LIFE Data and Safety Monitoring Board (DSMB) reviewed the above-named ancillary study proposal and made a motion to grant provisional approval provided that you address the major comments below. Please forward your response in writing to me by [2-week deadline from date of letter]. Your response will be reviewed and we will contact you when a decision has been reached.

You will be notified in writing upon final approval. Please note that you are not approved to begin data collection for your ancillary study or apply for external funding until you receive final approval.

Regards,

Marco Pahor, MD
Principal Investigator, LIFE Study

Jack Guralnik, MD, PhD
Co-Principal Investigator, LIFE Study

Appendix K – DSMB Revise/Resubmit Letter

Date

PI Name and Address

RE: Ancillary Study Proposal Title

Dear Dr. XXXXX:

The LIFE Data and Safety Monitoring Board (DSMB) reviewed the above-named ancillary study proposal and has requested that the proposal be revised and resubmitted based on the comments listed below. Please resubmit the revised proposal by [2-week deadline from date of letter]. Upon review of the revised proposal, you will be contacted regarding the DSMB's decision.

You will be notified in writing upon final approval. Please note that you are not approved to begin data collection for your ancillary study or apply for external funding until you receive final approval.

Regards,

Marco Pahor, MD
Principal Investigator, LIFE Study

Jack Guralnik, MD, PhD
Co-Principal Investigator, LIFE Study

Appendix L – DSMB Rejection Letter

Date

PI Name and Address

RE: Ancillary Study Proposal Title

Dear Dr. XXXX:

Thank you for submitting the above-named ancillary study proposal. The LIFE Data and Safety Monitoring Board reviewed the proposal and regrets to inform you that it has not been accepted based upon reasons listed below.

Regards,

Marco Pahor, MD
Principal Investigator, LIFE Study

Jack Guralnik, MD, PhD
Co-Principal Investigator, LIFE Study