Adult Changes in Thought (ACT) Research Program Proposals and Publications Policy and Procedures¹

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¹ Adapted from the Women's Health Initiative Publications and Presentations Policy, with permission.

Definitions of Key Terms

Scholarly work: an abstract or other presentation to a professional conference/meeting, a manuscript submitted to a scientific journal or similar (academic thesis, etc.) resulting from an analysis or synthesis of data

ACT Investigator: researcher funded by the ACT U19 grant

Internal ACT investigator: ACT investigator located/employed at KPWHRI (data remain behind the firewall)

External ACT investigator: ACT investigator not located at KPWHRI (data leave the KP firewall)

Ancillary Investigator: researcher using data outside of the U19 (e.g., ACT AIR, ACT EYE)

Internal request: request from an ACT investigator (either internal or external investigator)

External request: request from someone who is not an ACT investigator

ACT Data Repository: broadly defined as all data related to ACT research participants. At a high level, data sources that make up the ACT Data Repository include data collected directly by the ACT study, such as self-reported risk factor data, cognitive testing data, and research diagnoses produced by the ACT study team in the course of work directly with participants. Beyond these, the ACT Data Repository includes:

- Data derived from biospecimens
- Data from ancillary studies and data derived from samples/investigations from ancillary studies
- Data from clinical care at KPWA or other institutions
- Data that can be linked to ACT participants

Ancillary Study: encompasses research funded with a grant other than the U19 to analyze existing ACT data (secondary data analysis), curate new data sources not previously used in ACT, or collect new ACT data.

Feasibility Study: exploratory work that includes examination of available data to gauge whether ACT data are a good fit for a research question

Prep-to-Research Query: exploratory use of ACT Data utilizing the ACT Data Query Tool, and includes connection to an Ancillary Study request

Rapid Review: in exceptional circumstances, a process will be utilized in which the ACT U19 leadership agree to review a proposal on accelerated timeline

Data Use Agreement: a written contract used to govern the transfer of ACT Program research data between organizations, in this case, between KPWHRI and an external data requestor/recipient

Collaborative Research Agreement: ACT U19-specific form that sets forth terms and conditions under which ACT will disclose the Data Set or Data Tables to the Data Recipient

Abbreviations

- **ACT** Adult Changes in Thought Study
- AS Ancillary Study
- ASRC ACT Ancillary Study Review Committee
- Admin Core Administrative Core
- **EC** Executive Committee
- EHR Electronic Health Record
- KPWHRI Kaiser Permanente Washington Health Research Institute
- NIA National Institutes of Aging
- PI Principal Investigator
- P&P Committee Proposals and Publications Committee
- **UW** University of Washington

1. Overview

The Adult Changes in Thought (ACT) U19 Proposals & Publications Committee (P&P) Committee supports appropriate and scientifically sound use of ACT data and resources and tracks the dissemination of ACT study results.

The P&P Committee regularly reviews all internal and external requests to use ACT Repository Data for manuscripts and other scholarly works. The P&P Committee also reviews final drafts of manuscripts and other scholarly works that disseminate the results from analyses of ACT data. All proposed manuscripts and abstracts regardless of whether developed by an ACT investigator or outside researcher must be approved by the P&P committee prior to initiation and upon completion, before submission for publication or other means of dissemination (i.e., professional conferences, etc.).

Investigators are encouraged to propose and develop scholarly works. ACT has a rich set of data, and the study wants the data to be used and published widely. Investigators who are unaffiliated with ACT are required to work with an ACT investigator in developing their proposal and subsequent scholarly work. The ACT website includes <u>a list of ACT investigators</u>. Additional information about specific investigators and areas of expertise can be obtained by contacting <u>kpwa.actproposals@kp.org</u>.

When requesting ACT data for assessments of feasibility with a limited scope, internal U19 Projects, Cores and ACT ancillary studies (AS) with funded Kaiser Permanente Washington Health Research Institute (KPWHRI) programmers/biostatisticians do not need to follow processes described herein. Ancillary Study Proposals for grants to fund the use of existing ACT data, curate new data sources not previously used in ACT, or collect new data from ACT participants that are not included in the U19 are covered by the <u>Ancillary Study Policy</u> and not described herein.

ACT data are not available for any for-profit purposes. However, individuals working for a for-profit entity who want to use ACT data for a research, non-profit-related reason are encouraged to contact ACT to inquire whether the proposed use fits within ACT-approved uses.

2. Committee Structure, Term, and Meeting Schedule

The P&P Committee is composed of ~5-6 standing nominated representatives, ideally 1 from each U19 project (3 individuals in total), the Data & Analysis Core (2 individuals who can share responsibilities), the Admin Core (1 individual) and one of the remaining cores on an annual rotation (1 individual; cores will rotate in alphabetical order from C-E). A single individual may represent more than 1 project/core on the committee, as applicable and appropriate. Representatives from the ACT Data & Analysis Core review proposals with a particular focus on data availability and analytic appropriateness and complexity.

A pool of ad hoc reviewers representing those cores not currently serving on the committee along with back-up and secondary reviewers from standing cores and projects will be available to review proposals and attend meetings when a particular proposal requires their expertise. As needed, additional experts from the broader ACT investigator pool may be enlisted in ad hoc for review of a given proposal requiring expertise beyond that of the P&P Committee members.

The Committee is arbitrated and managed by a Chairperson who is nominated from the membership of the P&P Committee. All members, including the Chairperson, serve one-year terms which may be renewed.

The structure of the P&P Committee ensures it remains small enough to facilitate nimble discussion and decision making, while ensuring appropriate reviewers who are knowledgeable about the ACT Repository, the U19's overarching scientific and programmatic goals, and any applicable project/core expertise are available for all proposals.

The committee meets monthly. The meeting <u>schedule</u> includes associated submission deadlines.

3. Committee Responsibilities

The P&P Committee has delegated authority from ACT U19 leadership to review all requests to use data from the ACT Repository and/or U19 programming and analytic resources, and the scholarly works that result from these requests.

Responsibilities for P&P Committee members include:

- 1. Delivering timely, comprehensive reviews of submitted proposals and scholarly works prior to the monthly P&P Committee meeting date
- 2. Attending regularly scheduled meetings and providing input on proposals or scholarly works during the meetings
- 3. Preparing reviews for off-schedule assignments when they arise, and returning feedback to the P&P Coordinator within requested timeframe
- 4. Contributing to P&P policy, procedures, and training of new investigators in the P&P process

Members of the P&P Committee receive review requests via a standardized format from the P&P Coordinator, along with an accompanying review form to record responses and to support tracking.

If the Committee is unable to make a determination, or in the event of concerns regarding a proposal (e.g., for a previously unprecedented data use), issues may be escalated first to the ACT Executive Committee and, if needed, to the ACT U19 Multiple PIs to make a final determination.

4. Types of Reviews

The P&P committee reviews:

- Data Requests and Manuscript Proposals (<u>Section 5</u>) data requests related to proposed plans for manuscripts and other scholarly works
- Manuscripts (Section 8) final drafts of articles or similar prior to publication
- Abstracts (<u>Section 9</u>) intended submissions for scientific meetings
- Other data requests, such as for harmonization efforts, feasibility studies or preparatory research that cannot be accomplished with the ACT Data Query Tool (<u>Section 10</u>)

5. Procedures for Researchers Related to Data Requests and Manuscript Proposals

Researchers interested in using ACT data for an analysis leading to an abstract or manuscript should start by completing the <u>Data Request and Manuscript Proposal Form</u>. If a researcher plans to use one dataset for more than one scholarly work, separate proposal forms should be submitted for tracking purposes. The P&P Committee will link the proposals so as to facilitate and simplify the review process. Researchers should be mindful of deadlines for proposals submissions for P&P review according to the P&P meeting <u>schedule</u>.

Researchers may only use the requested ACT dataset to conduct the research described in the P&Papproved proposal. If researchers would like to use the data for another scholarly work or purpose (other than what is described in the proposal form), they should submit a new <u>Data Request and</u> <u>Manuscript Proposal Form</u>.

If the original scope of the proposal is later modified, researchers should submit an updated proposal form to the P&P Committee clearly indicating these changes. Based on the described modifications,

P&P may opt for one or more of the P&P committee members who initially conducted the review to rereview the updated proposal form, focusing primarily on the modified sections. Alternatively, if the updated proposal has changed substantially, P&P may decide that it merits a full re-review, and or may consider it a new proposal altogether.

Researchers with questions should contact the P&P Coordinator at kpwa.actproposals@kp.org.

5.1 Development of the Data Request and Manuscript Proposal

Prospective researchers are encouraged to work with their identified ACT collaborator during the proposal development process for the ACT collaborator's expertise/familiarity with what ACT data are (and are not) available; ACT data nuances, complexities, & limitations (e.g., missingness); as well as the P&P review process. The ACT collaborator can additionally help to ensure that the proposal is both feasible using ACT data sources and has the level of detail that P&P requires to conduct their review.

When relevant, prospective researchers are further advised to contact <u>ACT investigators who are</u> <u>content experts</u> in various domains of ACT to engage necessary expertise in specific areas of research. For additional information about specific investigators and areas of expertise, please email <u>kpwa.actproposals@kp.org</u>.

Prospective researchers are encouraged to utilize information about the <u>ACT Cohort</u> located on the ACT Study <u>website</u> and available ACT Study <u>data documentation resources</u>. The ACT <u>Data Query</u> <u>Tool</u> may facilitate identification of data variables and sample size calculations.

A full bibliography of <u>ACT publications</u> is available and should be reviewed by prospective researchers before developing a proposal so as to avoid overlap with an existing or prior proposal. If potential overlap is identified, the researcher is encouraged to contact the lead author of that proposal to determine if overlap can be avoided by revising the focus of the new proposal, or to discuss the possibility of joining the existing writing group should the lead author agree. If overlap is first identified *after* a proposal's approval, the authors may be asked to cease their work and, if possible, to integrate work on the two overlapping proposals.

5.2 Review Process for Data Request and Manuscript Proposals

The P&P Coordinator will add the proposal to the next P&P meeting agenda upon receipt of a completed <u>Data Request and Manuscript Proposal Form</u> from a researcher. Incomplete forms will be returned to the proposal leader for revision.

The P&P Chairperson assigns 3 committee members to review the proposal, with one serving as the primary reviewer who leads the discussion of the proposal during the P&P meeting at which it is discussed, and another as the secondary reviewer. Assignments for reviewers are made based on manuscript focus, matched to reviewer expertise. The third assigned reviewer from the ACT Data & Analysis Core is focused on reviewing data availability and analytic appropriateness and complexity.

P&P reviews data requests and manuscript proposals for:

- Scientific merit, significance, or rigor
- Feasibility
- ACT resources
- Data availability
- Participant burden
- KP staff burden
- Duplicative work

- ACT Researchers/collaborators involvement
- Alignment with U19 research
- Budget plans

Assigned reviewers will be given 2 weeks to review materials ahead of the P&P Committee meeting at which the data request and manuscript proposal is discussed.

If P&P Committee members are the first or senior (or otherwise major contributing) author among the writing group members, they should recuse themselves from any review of and decisions related to the data request and manuscript proposal. Such individuals may, however, participate in P&P Committee discussions about the proposed manuscript to provide clarifications and more in-depth information.

P&P members record their review responses on a standardized form with their individual recommendation of either approve, revise and resubmit or disapprove. All reviews are confidential, and committee members should not use information from a proposal to further their own work.

Responses are collated by the P&P Coordinator and circulated to all P&P Committee members on the agenda for the P&P Committee meeting in advance of the meeting.

After the proposal is considered and discussed at the meeting, the committee will reach consensus on the course of action for the data request and manuscript proposal including approve, revise and resubmit, or disapprove. Feedback and recommendations from P&P reviewers are provided to prospective researchers within one week after the meeting during which the proposal was reviewed.

If a revise and resubmit is recommended, prospective researchers should submit their revised proposals to the committee for a second P&P review ideally within 3 months. Researchers are instructed to use a track changes or similar approach to highlight the revisions to their proposal.

Once a proposal is approved, researchers will finalize their dataset needs with the Data & Analysis Core and receive their dataset. Researchers are required to sign and execute the <u>ACT Collaborative</u> <u>Research Attestation & Data Use Agreement</u> (if external to KPWHRI) to conduct their research using the ACT data.

6. Manuscript Writing and Preparation

After a data request and manuscript proposal is approved by the P&P Committee, a writing group of co-authors may be formed, which includes the authors listed on the proposal and other researchers who are interested in participating and who have expertise in the proposal's subject area. The writing group formation process is described in <u>Section 7</u>.

The P&P Committee works to ensure consistency among ACT publications. Authors are asked to follow the <u>ACT Guidelines for Manuscript Development</u> when writing manuscripts and appropriately cite the ACT funding sources described in the <u>Manuscript Acknowledgement Guide</u>.

Authors are expected to submit a final draft manuscript for Committee review within 12 months of receipt of requested ACT data and prior to submission for publication. If the resulting manuscript is not prepared within 12 months, the lead authors should provide an explanation to the P&P Committee as to why they were unable to do so to request an extension. Multiple extensions through this annual review process may be possible if the P&P Committee deems this appropriate.

Should the manuscript related to an approved proposal fail to be ready for publication within three years of its initial approval, the P&P Committee will meet with the lead author to aid in moving the manuscript to publication. In certain rare cases, a new lead author may be recommended.

To ensure timely completion of manuscripts, authors are discouraged from leading more than three papers at one time. Petitions for exceptions to this rule may be sent to the P&P Coordinator at <u>kpwa.actproposals@kp.org</u> and will be reviewed by the P&P Committee.

7. Writing Groups and Authorship

The ACT Study follows recommendations for authorship issued by the International Committee of Medical Journal Editors which specify that authorship credit is based on the following four criteria:

- a) Substantial contributions to conception, design, or acquisition of data or analysis and interpretation of data, such as providing statistical expertise, obtaining funding, providing administrative, technical or material support, or supervision;
- b) Drafting the article or revising it critically for important intellectual content;
- c) Final approval of the version to be published;
- d) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

7.1 Selection and Formation of Writing Groups

Once P&P approval for a manuscript proposal is granted, information about the proposal will be circulated to ACT investigators and interested researchers may nominate themselves or a qualified colleague to participate in a writing group. Writing group nominations should occur within the following one month and are sent directly to the lead author. Lead authors are responsible for updating the P&P Coordinator with the final writing group membership for tracking purposes.

Criteria for selection of writing group members will include level of expertise (related to the manuscript topic), support of authorship by early career scientists, balanced representation across ACT-affiliated institutions, and consideration of individual commitments to other ACT writing group endeavors. All authors must make a substantive contribution to the manuscript. Contributions can include scientific contribution to the project development, participant recruitment, protocol development, and ongoing data collection as well as expertise in the content area.

The following guidelines apply to writing group formation:

- The researcher submitting the proposal for approval (the lead author) is chair of the writing group.
- The number of authors per paper are not restricted by the P&P Committee; however, researchers are encouraged to keep in mind the limitations established by their target journal. If more than a reasonable number of authors are nominated for a particular writing group, the lead author can use their discretion to limit the group to a reasonable number of authors and provide rationale for specific nominees to be excluded.
- At least one ACT investigator should be invited to participate in a writing group.
- The primary statistical analyst on the project is typically included as an author.
- Ancillary Study investigators should be invited to participate in the writing group of a manuscript involving Ancillary Study data.

Advanced graduate students who have a major involvement with development of a proposal as a part of their thesis work are eligible to participate in writing groups. Graduate students who serve as the lead author should be mentored by an experienced ACT investigator who is willing to oversee the paper.

7.2 Writing Group Conduct

The writing group chair has the following responsibilities:

- Establish a plan for writing the manuscript
- Contact writing group members and delegate tasks.
- Finalize the analysis plan.
- Obtain input from every member of the group (including the lead statistician) during manuscript development.
- Keep the P&P Committee informed of the paper's progress (notify P&P of any delays or departures from the established schedule, providing explanations for any delays that do occur, etc.) If problems emerge, P&P will confer with the writing group chair to resolve the situation.
- Assure that all authors have reviewed the manuscript prior to submission to P&P.
- Inform the P&P Committee of any substantial minority opinions or reports within the writing group that cannot be resolved within the writing group. (This is intended to ensure that serious concerns are not arbitrarily overruled by the writing group chair without the knowledge of the P&P Committee.)
- Contact a prospective author to inform them they have been removed from the writing group if that member does not respond to the writing group chair's requests or does not contribute to the paper. Inform the P&P Committee of changes to writing group membership.
- Submit the final draft paper to the P&P Committee for review.
- Submit the paper to a journal for publication within 3 years of the related data request and manuscript proposal's approval by the P&P Committee.

Writing group members have the following responsibilities:

- Participate actively in the preparation of the manuscript.
- Respond to requests from the writing group chair throughout manuscript development within the timeframe requested. If a writing group member is unable to meet such deadlines, they should inform the writing group chair immediately and the chair must decide if the member can maintain authorship given the inability to meet the set deadlines.
- Review and approve the final draft manuscript before it is submitted to the P&P Committee for final review and before it is submitted to the target journal.

7.3 Appeals Related to Writing Groups

If one or more writing group member(s) disagree(s) with the data analyses, interpretation of the data, or authorship, the member(s) should discuss the disagreement with the lead author, who will make a decision on how to resolve the dispute. If the disagreement cannot be resolved within the writing group or the lead author is not responsive to the request for changes, the writing group member should ask for a polling or formal vote of the entire writing group relating to the issue in dispute. If this does not resolve the issue, and the writing group member believes that it is in the best interests of ACT not to allow the paper to proceed, an appeal may be made to the P&P Committee Chair, who will attempt to resolve the issue or appoint an appropriate P&P member to resolve the issue in a meeting with the lead author and the member(s) who are in disagreement. If this is unsuccessful, and if the P&P Committee Chair, with the approval of the committee, cannot make a decision, then the P&P Committee Chair should solicit expert opinion from within ACT, and, if necessary, from outside the study. If final arbitration is necessary, the P&P Committee through the chair will notify the ACT Executive Committee (EC) of the issues under discussion, and the EC will make the final decision. If ultimately changes are not recommended or made in response to substantial minority opinions, the writing group member(s) with the dissenting opinion(s) can choose to remove themselves as an author(s) from the paper.

8. Review Process for Manuscripts

All manuscripts that include ACT data must be reviewed and approved by the P&P Committee prior to their submission to a journal for publication.

To initiate the P&P review process, authors complete designated sections of the <u>Manuscript Checklist</u> and <u>Review Form</u> and submit to the P&P Committee along with their manuscript in final draft form. The P&P Coordinator will add the manuscript to the next P&P meeting agenda upon receipt of complete materials from author.

Manuscript authors should be mindful of deadlines for manuscript submissions for P&P review according to the P&P meeting <u>schedule</u>.

Upon receipt of a final draft manuscript, the P&P Chairperson assigns reviewers following a similar process to that described for manuscript proposals in <u>Section 5.2</u>. When possible, reviewers of the original data request and manuscript proposal are assigned to review the final draft manuscript. Co-authors of the manuscript who are also P&P Committee members are not eligible for review assignment of their own manuscript. Reviewers adhere to a similar timeline to that also described for manuscript proposals in <u>Section 5.2</u>.

In evaluating manuscripts in final draft form, P&P Reviewers consider the following criteria:

- The description of the ACT Research Program data repository and other research resources are consistent with language provided in the Manuscript Acknowledgement Guide and on the ACT website.
- The cohort/sub-population is described using standard ACT descriptions when possible; inclusion and exclusion criteria used to construct the analytic dataset are explained.
- Descriptions of methods and results are consistent with ACT's guidelines for statistical methods and reporting in the Guidelines for Manuscript Development.
- Presented analyses reflect what was proposed by the author(s) without substantial deviation (please refer to approved proposal).
- Analyses are without major methodological or data errors, and results are interpreted appropriately.
- The authors discuss how previous findings from ACT studies impact their current work if there is overlap, and key ACT publications are referenced in the bibliography.
- Acknowledgements of the ACT Research Program grant numbers, research volunteers and reference to ACT website are accurate and appropriately included.

Reviewers record their evaluation on designated sections of the <u>Manuscript Checklist and Review</u> <u>Form</u> with their individual recommendation of either approve, revise and resubmit or disapprove.

Responses are collated by the P&P Coordinator and circulated to all P&P Committee members on the agenda for the P&P Committee meeting in advance of the meeting.

After the draft manuscript is considered and discussed at the meeting, the committee will reach consensus on the course of action for the manuscript including approve, revise and resubmit, or disapprove. Feedback and recommendations from P&P reviewers are provided to authors within one week after the meeting during which the manuscript was reviewed.

If a revise and resubmit is recommended, authors should submit their revised manuscript to the committee for a second P&P review ideally within 3 months.

Once authors have received notification that their manuscript has been approved by the P&P Committee, they may submit the paper for journal publication.

8.1 Publication of Manuscripts

The manuscript lead author is responsible for keeping ACT updated of the manuscript's status on an ongoing basis, this includes when the manuscript is submitted to a journal, accepted for publication, and expected publication dates. Authors do not need to involve the P&P Committee while the manuscript is being reviewed and revised for a journal during the course of publication unless substantial changes have been made to the methods. Instructions for these notifications are included in an informational memo to authors that accompanies the P&P notification of the final draft manuscript approval.

It is expected that authors will share with P&P a copy of the manuscript as accepted by the journal and the published manuscript in PDF form as they become available.

NIH Public Access Policy applies to ACT manuscripts stemming from contracts funded in or after April 7, 2008, as well as all ACT manuscripts on which an NIA employee is a coauthor. Lead authors are responsible for ensuring their manuscripts conform to these guidelines promptly. Authors should refer to the NIH policy website at http://publicaccess.nih.gov/index.htm for current regulations.

Publications and presentations shall be in compliance with the rules and procedures of disclosure set forth in the Privacy Act. Confidential or proprietary information shall not be disclosed without the prior written consent of the individual or institution. Privacy Act compliance and documentation of written disclosure consents are the responsibility of each institution involved in the publication/presentation.

9. Review Process for Abstracts

All abstracts must be reviewed and approved by the P&P Committee before they are submitted to any local, national and/or international conferences or meetings. Authors should submit abstracts for P&P review a minimum of one week prior to the abstract deadline (two weeks is preferred). All abstracts must be derived from P&P-approved data request and manuscript proposal or submitted for review concurrently with the related proposal.

To initiate the P&P review process, authors complete designated sections of the <u>Abstract Checklist</u> and <u>Review Form</u> and submit to the P&P Committee along with their abstract in final draft form. Upon receipt of complete materials from author, the P&P Chairperson assigns two reviewers to the abstract, with an aim of matching relevant expertise. Whenever possible, preference is made in the assignment of reviewers who originally considered the data request and manuscript proposal from which the abstract resulted. Co-authors of the abstract who are also P&P Committee members are not eligible for review assignment of their own abstract.

Review of abstracts receive a faster and more abbreviated review and so are not required to adhere to the timing of the regular P&P Committee meeting schedule. Abstracts are circulated by email to reviewers with a request to complete their review within one week. Expedited reviews (i.e., those to be completed in less than one week) may be requested but will only be fulfilled if reviewers with appropriate expertise can be identified and are willing to meet the shorter timeline.

In evaluating abstracts, P&P Reviewers consider the following criteria:

- The ACT Research Program description is consistent with those provided in the <u>Manuscript</u> <u>Acknowledgement Guide</u> and on the ACT website as space allows.
- Analyses are of sufficient rigor and reflect what was proposed by the author(s) in the corresponding and previously-approved ACT proposal, and results are interpreted appropriately.
- The authors indicate an intention to properly acknowledge appropriate ACT grants, website URL, and research volunteers in their final abstract/presentation following guidelines in the <u>Manuscript Acknowledgement Guide</u>.

Reviewers record their evaluation on designated sections of the <u>Abstract Checklist and Review Form</u> and submit to the P&P Coordinator. Feedback and recommendations from P&P reviewers are provided to authors within one week after responses are collated by P&P.

On occasion, the P&P allows abstracts to be submitted to a conference or meeting without prior P&P review and approval, this with the understanding that authors will withdraw the abstract or make required changes if the reviewers and the P&P Chairperson deem this necessary.

10. Requests to Use ACT Data for Other Purposes and Related Review Procedures

Requests to use ACT data for another purpose (e.g., harmonization efforts, feasibility studies or preparatory research that cannot be accomplished with the <u>ACT Data Query Tool</u>), or for theses, dissertations, and other academic projects follow the described processes for data requests and manuscript proposals.

10.1 Theses, Dissertations, and Other Academic Projects

Graduate students who use ACT data for an academic project should include an ACT investigator as a mentor. ACT data may not be used by students if the data relate to major ACT papers in progress or if the P&P Committee deems those 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 group is established with the student as chair. The writing group 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 advisor is to report the student's progress to the P&P Committee a minimum of once annually. ACT reserves the right to proceed with preparing a paper on the thesis/dissertation topic for publication through the activation of a writing group if, in the view of the P&P Committee and the student's advisor, the student has not made reasonable progress in completing the thesis.

The completed thesis/dissertation must include (1) a statement acknowledging ACT for use of the data and (2) a statement indicating that opinions, ideas, and interpretations included in the thesis are those of the student alone and not those of the ACT investigators. When the thesis has been completed, as determined by the advisor, the entire writing group will develop the manuscript(s) for publication. The sponsoring ACT investigator will ensure that the thesis/dissertation accurately reflects the conduct and data from ACT.

10.2 Review Articles, Book Chapters, and Editorials

Review articles, book chapters, and editorials do not generally need to be reviewed by the P&P Committee; however, if these scholarly works may be seen to conflict with conclusions from previously approved ACT publications, they should be submitted for review. If in doubt, authors are encouraged to submit a draft of the work (or an outline of the area of possible contention) to the P&P Chairperson for an initial screening so it can be assessed if full review is needed.

When a full review by the P&P Committee identifies concerns, and the authors wish to publish or present the work without addressing those concerns, the authors are requested to include a statement to the effect that "the opinions expressed in this publication (presentation) are those of the authors, and do not necessarily represent the opinions of other ACT investigators." The authors may not list NIA support of the work in such a case.

10.3 Media Materials

While P&P does not review press releases, talking points, or other media materials, researchers should contact ACT at <u>kpwa.actproposals@kp.org</u> before releasing any ACT-related information to the press, and ACT will assist with bridging the connection with KPWHRI's Media Relations.

10.4 Data for Illustrative Purposes

Requests to use ACT data for purely illustrative purposes should be directed to the P&P Committee Chairs. The committee will act on the request with due attention to the requester's link to the ACT and to the potential impact on other ACT-related publications and presentations.

11. Appendix

- <u>Collaborative Research Agreement</u>
- Data Use Agreement
- Data Request and Manuscript Proposal Form
- <u>ACT Guidelines for Manuscript Development</u>
- Manuscript Acknowledgement Guide
- Manuscript Checklist and Review Form
- Abstract Checklist and Review Form