ACT Proposals, Publications, and Presentations Policy[1]

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 by regularly reviewing all internal and external requests to use ACT Repository Data for new grant proposals, analyses, presentations, and manuscripts.

The P&P Committee is responsible for oversight of all requests to use ACT data and for the publications, presentations, and grant proposals that result from these requests.

Investigators, both those affiliated with ACT and those with no ACT affiliation, are encouraged to propose and develop publications and presentations. ACT has an incredibly 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 investigation in developing their proposal and subsequent manuscript, presentation, or grant. A list of ACT investigators can be found here. (Note: current link is to https://actagingstudy.org/about/research-program, which is not a list of investigators. We will need to add this to the website.) Additional information about specific investigators and areas of expertise can be obtained by contacting *kpwa.actproposals@kp.org.*

An ACT publication, presentation, or grant proposal is defined as any publication, presentation, or grant proposal that includes ACT data, whether developed by an ACT investigator or an outside researcher. All such proposed projects must be approved by the P&P committee prior to initiation.

Investigators interested in using ACT data should start by completing the Data Request Form, found here: https://actagingstudy.org/collaboration/work-with-us-1.

2. Committee Structure and Function

The P&P Committee is comprised of 5-6 standing nominated representatives from each U19 project (3 individuals), the Data & Analysis Core (1 individual), 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. Additionally 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 as needed when a particular proposal requires their expertise. This structure ensures the P&P committee 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. As needed, additional ad hoc experts from the broader ACT investigator pool may be enlisted for a given proposal. The Committee is arbitrated and managed by a Chair nominated from the membership of the P&P committee, serving a one-year term. All members, including the Chair, serve one-year terms which may be renewed. The committee meets monthly, and a meeting schedule, along with associated submission deadlines is available here: https://actagingresearch.org/collaboration/work-with-us-1/p-p_committee

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

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 for a grant proposal, publication, or presentation. If the Committee is unable to make a determination for a given proposal or manuscript, 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 Steering Committee and, if needed, to the ACT U19 Multiple PIs to make a final determination.

Members of the P&P Committee will receive all requests to use ACT Repository data via a standardized format from the P&P Program Manager, along with a P&P Review Checklist and Approval Form that will support tracking. Approval by the P&P Committee is required before analyses or data release can commence.

Requests to use ACT data will be reviewed for:

- Scientific rigor
- Alignment with ACT U19 research objectives
- Non-duplication with existing ACT research or ACT planned primary papers
- Feasibility, data availability, and analytic resources required to complete the request

Responsibilities for P & P Committee members include:

1. Delivering timely, comprehensive reviews of submitted proposals and manuscripts prior to the P&P Committee call date
2. Attending assigned calls, providing input on policy/procedures and/or proposals or full manuscripts
3. Preparing thorough reviews for off-call assignments (abstracts, revised proposals and papers, and posters), and returning feedback to the P&P Coordinator in a reasonable timeframe (7-10 days)
4. Contributing to P&P policy, procedures, and training of new investigators in the P&P process.

The P&P committee will review the following types of documents. Additional details on each of these document types is outlined below.

• *Manuscript Proposals* – proposed plans for manuscript development (including proposals from either ACT investigators or external investigators)
• *Manuscripts* – final drafts of articles or book chapters that are not yet submitted to a journal
• *Abstracts & Presentations* – summaries of intended presentations or posters for scientific meetings
• *Ancillary Study Proposals* – ancillary studies are defined as any grant that has funding separate from the ACT U-19 and either: 1) uses existing ACT data or 2) collects new data from ACT participants. The approval processes differ for the two types of ancillary studies. However, both types require approvals prior to submission to a funder. (See separate policy regarding creating ancillary study proposals here.) (Need link)

3. P&P Review Process and Guidelines

3.1 Manuscript Proposals

3.1.1 Information for Authors

All proposals must be reviewed and approved by the P&P Committee prior to development of an ACT manuscript. All materials related to submission of a manuscript proposal are available on the ACT website (https://actagingstudy.org/collaboration/work-with-us-1*)* or from the ACT P&P Coordinator. (*kpwa.actproposals@kp.org.)* A list of all ACT publications, approved proposals and approved manuscripts to date is available on the website at the following address: https://actagingstudy.org/news-

and-results/publications-database. Prospective authors should review this list before developing a proposal to avoid overlap. *(Note: As of 6/1/2022. the publications database is not yet available on the public website, but this work is ongoing and should be available in the coming months.)*

Authors are advised to contact Content Experts in various domains of ACT to engage necessary expertise in specific areas of research and to avoid the risk of duplication with previously published manuscripts or ongoing research as they develop their proposals: https://actagingstudy.org/about/research-program. For additional information about specific investigators and areas of expertise, please email: kpwa.actproposals@kp.org. Authors are also strongly encouraged to contact Ancillary Study PIs to engage them in any new proposals that will use data generated from a specific Ancillary Study.

If overlap is identified the prospective author may either drop the idea, contact the lead author of the proposal to determine if overlap can be avoided through selective data analysis and reporting, or discuss the possibility of joining the writing group should the lead author agree. A summary of these discussions should be forwarded to the P&P Chair for final approval. This will ensure appropriate documentation is completed for ACT P&P records. Even if overlap should first be identified following a proposal's approval from the P&P Committee, the authors may be asked to cease their work or, if possible, to integrate the two overlapping proposals.

To ensure timely completion of manuscripts, investigators are discouraged from leading more than 3 papers at one time. Petitions for exceptions to this rule may be sent to the P&P Coordinator (*kpwa.actproposals @kp.org)* and will be reviewed by the P&P Committee.

All definitions, criteria, and data to be used in the manuscript should be included in the proposal. Statistical power estimates should also be included whenever possible or an estimated likelihood of adequate sample size based on available ACT "cases" relative to published studies with similar associations and/or from data obtained using the ACT Data Query Tool (https://act.kpwashingtonresearch.org/dqt/).

Prospective authors are encouraged to work with their identified ACT collaborator during the proposal development process to enhance the quality of the analytical plan, assure sample size for statistical power, ensure consistency in definitions of derived variables, and to begin to formulate a thoughtful approach to data analysis.

Detailed information on what data have been collected at baseline and during follow-up is available in the "Data documentation" section on our website. (add link)

The P&P Committee generally does not approve broad proposals to analyze multiple outcomes/endpoints. It is recommended that authors focus on one endpoint per manuscript.

If an investigator would like to draft more than one manuscript based on a single approved proposal, a formal request must be sent to the P&P Committee; a new manuscript number will be assigned if the request is approved, and a new abbreviated proposal will be requested for tracking purposes but will generally not be required to undergo a full committee review.

3.1.2 P&P Committee Review Process

Upon receipt of a manuscript proposal, the proposal is added to the next available agenda. The P&P Committee Chair assigns 3 committee members to review the proposal for scientific merit, analytic issues, policy issues, concerns regarding interpretation of findings, overlap with other ACT papers, etc., using a standard review form. Assignments for reviewers are made based on manuscript focus, matched to reviewer expertise. Typically, one of the assigned reviewers will be a representative from the ACT Data &

Analysis Core, who will review proposals with a particular focus on data availability and analytic appropriateness and complexity. Content experts may be brought in as needed to review individual requests requiring expertise beyond that of the P&P members. Assigned reviewers will be given 2 weeks to review documents ahead of the next scheduled P&P Committee meeting at which the proposal may be discussed if necessary.

All reviews are confidential, and committee members will never use information from a proposal to further their own work.

After review, the committee will decide on the recommended course of action. Possible recommendations include: approved, approved with recommended changes, approved with required changes, revise and resubmit to primary reviewers, revise and resubmit to full committee, and disapproved. Committee recommendations and reviews are provided to prospective authors within one week after the call on which the proposal was reviewed.

If additional committee review is recommended, prospective authors should submit their revised proposals to the committee for a second review ideally within 3 months. If a proposal is designated for review to primary reviewers, those reviewers will be given 2 weeks to complete reviews.

Once a proposal has received committee approval, a writing group is formed, which includes the authors listed on the proposal and other investigators who are interested in participating and who have expertise in the proposal's subject area. The writing group formation process is described below.

3.1.3 Manuscript Submission Timeframe

Once a proposal is submitted and approved by the P&P Committee and statistical analyses have begun, the authors are expected to submit the final manuscript for Committee review within twelve months of receipt of data. If the resulting manuscript is not prepared within 12 months, the lead authors should provide an explanation of 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 an approved proposal fail to move to publication within three years of its initial approved proposal notification from the P&P Committee, 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.

3.2 Final 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. Submissions of manuscripts to P&P for review must follow the posted deadlines: (add link).

Upon receipt of a final manuscript, the committee follows a review process similar to the one described above for proposals. Once authors have received notification that their manuscript has been approved by the P&P Committee, they may submit the paper for journal publication. If their manuscript is accepted for publication, authors are expected to notify the P&P Committee of the acceptance and expected publication dates.

3.3 Abstracts and Presentations

All abstracts must be approved by the P&P Committee before they are submitted to any local, national and/or international conferences or organizations. When feasible, they should be submitted 1 to 2 weeks

prior to the abstract deadline. All abstracts must be derived from P&P-approved proposals or submitted for review concurrently with the related proposal.

Abstracts will be circulated by email to 2 P&P Committee members with relevant expertise, with a request to complete their review within 1 week. When an abstract is derived from a previously reviewed proposal, the same reviewers from that proposal will be assigned to review the resulting abstract whenever feasible, to maximize efficiency of review. Expedited reviews to be completed in < 1 week may be requested but will only be completed if reviewers with appropriate expertise can be identified and are willing to meet a shorter timeline.

On occasion, the P&P has allowed abstracts to be submitted without prior P&P review with the understanding that authors will withdraw the abstract or make required changes if the reviewers and the P&P Chairs deem this necessary.

The P&P Committee reserves the right to review posters and slides before presentation. Lead authors will be informed at the time of abstract approval if this will be required.

3.5 Ancillary Study Proposals

3.5.1 Grant proposals for secondary analysis of existing ACT data using external funding

Investigators intending to submit a grant proposal to fund analysis of existing ACT data must complete a Data Request Form and obtain P&P approval prior to submitting the grant proposal. This request form includes the Research Aims, a rough outline of proposed manuscripts and analytic approaches, and a high-level list of types of data needed. The proposal should include enough information for the P&P committee to determine: 1) scientific rigor; 2) alignment with ACT research objectives; 3) non-duplication with existing ACT work; and 4) feasibility, data availability, and ACT resources required to complete the request.

The Request Form may also include a request for Preliminary Data, if this is needed to complete the grant.Upon approval of the ancillary study proposal, any associated Preliminary Data requests will be added to the queue for fulfillment.

Investigators, at their discretion, may include a draft of the grant proposal in support of the background and detailed data analysis components of the manuscript proposals, but they are expected to draft summaries of these sections that adhere to the proposal page limits.

All such proposals must include an ACT investigator as one of the Co-I's.

If the initial proposal is approved by P&P, the investigators may submit a draft letter of support for the P&P Chair to edit and sign or the P&P Committee Chair will draft and provide a signed letter of support as appropriate for submission with the grant.

If the grant is ultimately funded, the lead investigator will complete 2-3 separate paper proposals using the ACT data request form for P&P review. Once these papers have been completed, the lead investigator may submit additional proposals for additional papers based on the grant to the P&P Committee. Manuscripts stemming from these ancillary analyses will adhere to the full P&P review process; that is, manuscript proposals, abstracts, and draft manuscripts are submitted to the P&P Committee for review

If the funding request is not approved, the investigators will need to inform the P&P Committee within 18 months as to whether they will pursue the proposed manuscripts. If they do not wish to proceed, other ACT investigators may submit proposals based on the aims in the grant.

If the grant includes new reading or processing of ACT scans or biospecimens, this should be indicated on the Data Request form and will entail an additional review by the applicable Project/Core lead responsible for the requested data/specimens. If deemed necessary due to resource constraints or concerns, such requests may also require review by the ACT Executive Committee, similar to the process for review of grants proposing new data collection (section 3.5.2, below).

3.5.2 Grant proposals that include collection of new data from ACT participants

Due to the age of ACT participants and the length of the ACT exams, proposals to collect additional data from ACT participants are rarely approved. Investigators interested in submitting this type of Ancillary Study proposal must complete the Ancillary Study Request Form, found here. This request form requires approval from the ACT Executive Committee prior to submission to the granting agency. Please refer to the Ancillary Studies Policy (in draft) for details of the steps required prior to submitting a grant proposing new data collection on ACT participants.

Maintaining the integrity of ACT, retaining study participants, and adhering to ACT protocols are of paramount importance; any proposed ancillary study that would interfere with ACT procedures, involve unreasonable participant burden, or possibly lead to participants leaving the study early is unlikely to be approved.

Review criteria:

- Scientific merit
- Burden on ACT participants or biospecimens
- Requires the unique characteristics of ACT participants
- Does not negatively impact ACT main objectives

If approval is granted by the Executive Committee, the P&P Committee is notified, and the grant proposal is entered into the P&P database for tracking. No approvals from the P&P Committee are required prior to submission for funding, but if the grant is funded, any manuscripts arising from the ancillary study are required to follow the manuscript proposal policies outlined above.

If an ancillary study is not funded, the PI should notify the P&P Committee of this result and whether or not the grant will be resubmitted, for tracking purposes.

3.6 Other types of requests

3.6.1 Proposals using downloadable data sets

Proposals stemming from downloadable ACT datasets must be reviewed by the P&P Committee. Once approval is granted, the investigator will be given time-limited login permissions to access the data.

Manuscripts stemming from public datasets that are initiated by investigators external to ACT are not required to undergo review by the P&P Committee. However, the Committee prefers those draft proposals be sent to the P&P Committee for their records. Manuscripts stemming from public datasets led or co-authored by an ACT investigator must be reviewed by the P&P Committee.

3.6.2 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 papers 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 Chairs for an initial reading so they can decide if full review is needed.

If upon review 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.

3.6.3 Media Materials and Talking Points

Items in these categories are not reviewed by P&P. However, anyone developing a press release, talking points, or other media material should work with the Kaiser Permanente Public Relations department (need link) before releasing any ACT-related information to the press.

4. Writing Groups

4.1 Selection and Formation

Once P&P approval for a manuscript proposal is granted, the proposal will be circulated to ACT investigators so that interested investigators may nominate themselves or a qualified colleague to participate in a writing group. Writing group nominations will be sent directly to the lead author. Lead authors are responsible for updating the P&P database with the final writing group for tracking purposes.

The following guidelines apply to writing group formation:

- The investigator submitting the proposal for approval (the lead author) will be appointed chair of the writing group.
- The P&P Committee does not restrict the number of authors per paper; however, investigators are encouraged to keep in mind the limitations established by their target journal. Most manuscripts should include 4 - 7 authors. If more than 7 are nominated for a particular writing group, the lead author can use their discretion to limit the group to a reasonable number of authors.
- 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.
- At least one ACT investigator should be included in every writing group.
- The primary statistical analyst on the project is typically included as an author.
- 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.
- Authorship on Ancillary Study papers will always include Ancillary Study investigators and may also include other ACT investigators.

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, but they must be sponsored by an experienced ACT investigator who is willing to oversee this process.

Papers using public datasets typically originate outside of ACT, and as such, the lead author may constitute the writing group as they desire.

4.2 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.
- Maintain contact with the assigned statistician (if ACT analysts are doing the analyses).
- Convene a meeting of the writing group to finalize the analysis plan.
- Keep the P&P Committee informed of the paper's progress (notify the P&P Chairs of any delays or departures from the established production schedule, providing explanations for any delays that do occur, etc.) If any problems emerge, the P&P Committee will confer with the involved writing group chair to resolve the situation.
- Inform the P&P Committee of any substantial minority opinions or reports 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.) Assure that all authors have reviewed the manuscript prior to submission to P&P.
- Submit the final paper to the P&P Committee for proposal and/or draft manuscript review.
- Submit the paper to a journal for publication within 3 years of the proposal's approval from the P&P Committee.

Members of each ACT writing group should participate actively in preparation of the publication assigned to that group. The writing group chair must obtain input from every member of the group during manuscript development. In addition, all members must review and approve the final draft manuscript before it is submitted to the P&P Committee for review. If any member of the writing group does not respond to the writing group chair's requests or does not contribute to the writing of the paper, the chair should contact the prospective author to inform them they have been removed from the writing group.

4.3 Appeals

If one or more writing group member(s) disagree(s) with the data analyses, interpretation of the data, or authorship, the members 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 Steering Committee of the issues under discussion, and the SC will make the final decision.

5. Manuscript Content

5.1 General Guidelines

The P&P Committee works to ensure consistency among ACT publications. The following guidelines apply to all papers:

- All publications should reference the global paper and/or any other relevant publications from ACT. (Global paper: … need ref or refs here)
- Conclusions concerning individual outcomes should be presented in a way that considers the global outcome.
- Definitions of dementia endpoints and major comorbidities (e.g., cardiovascular disease, hypertension and diabetes) should be consistent with the major primary outcome paper; if defined differently, the distinction should be emphasized in the presentation.
- The prescribed acknowledgement section must be included. [See section below.]

5.2 Writing Clarity

P&P Reviewers will consider the following when examining draft papers and proposals:

- Does the paper's topic overlap with existing literature? If so, do the authors reference those findings and discuss how they impact their current work?
- Are power calculations provided if appropriate?
- Are tables and graphs relevant and well-labeled?
- Is the writing clear and readable?

5.3 Statistical Guidelines

The following guidelines concern statistical issues:

• Two-sided p-values should be used.

• Avoid interpreting results based upon statistical significance alone. Consider scientific context, plausibility, magnitude of effects, and clinical importance of observed differences.

• In situations where results were consistent with 'no difference', describe whether results were indeterminate (in need of further study), or were negative (clinically meaningful differences were ruled out).

• Subgroup analyses should report number of subgroups and address the possibility of excessive Type I error, by stating the number of comparisons that could be significant by chance alone.

• The statistical significance of subgroups should be assessed by tests of the interaction terms between exposure x subgroups. There may be limited power for testing interactions, and this should be addressed in the discussion.

• Forest plots of hazard or odds ratios should be scaled such that HR estimates of ½ and 2 should be visually equidistant from unity.

• When applicable, Kaplan-Meier curves should be presented as cumulative incidence rather than disease-free survival and should include a suitable amount of follow-up time.

• For observational studies, plots of cumulative HRs over time may be more suitable than overall HRs because Cox regression models readily allow for time-dependency in HR models.

• Issues of sequential monitoring and multiple testing should be considered and noted in the study plan and addressed in the discussion. An acknowledgment of the potential for over-interpretation of results will suffice.

• For reports that consider many outcomes, nominal CIs and nominal p-values alone may be presented, but the text should address the possibility of excessive Type I error, by stating the number of comparisons that could be significant by chance alone.

• Consider presenting estimates of the exposure's effect in both absolute and relative terms so results are more comprehensive and interpretable. For example, when reporting hazard ratios, also report the number of events and annualized rates. Difference in estimated absolute risks (e.g., exposure minus control group) per 10,000 person years may provide additional context.

• Longitudinal analyses should be considered if response data were collected at more than 1 time point. Common longitudinal methods include likelihood models (e.g., linear mixed effect [LME] models) and generalized estimating equations (GEEs) that account for within participant correlations over time, preferably so that temporally closer observations are more strongly correlated; random intercept models and compound-symmetric variance-covariance matrices are typically not sufficient.

• Missing data and length of follow-up should also be considered when selecting a longitudinal method. GEE models assume that data is missing completely at random, which is often a problematic assumption. LME models make weaker assumptions regarding missing data. Inverse non-missingness probability weighting may be considered for incorporation into any of these methods for a more substantial missing data provision.

• Avoid making comparisons at every time point. Instead, a single omnibus statistical test or contrast that compare exposure groups (e.g., constant treatment effect; weighted average of effects at each time point) may provide better inferences and better provision for multiple comparisons.

5.4 Reporting Diversity and Ancestry Data

5.4.1 Overarching principles:

Race and **Ethnicity** are distinct socio-political constructs that are **not** rooted in **biology**. **Ancestry** and **genetic admixture** are **not** interchangeable with "race" or "ethnicity".
Ethnicity is distinct from **Race**. Both should appear in ACT characteristics tables.

5.4.2 Race and Ethnicity Definitions and Terminology (Language)

Individuals should be referred to by their self-identified race and ethnicity. Terms used to group race and ethnicities should be well conceptualized in the manuscript.

5.4.3 ACT Cohort Representativeness of U.S. Older Adults by Age and Race and Ethnicity

Authors should address the representativeness of the U.S. older adult population, per Census data, of the ACT cohort when interpreting analytic results.

5.4.4 Specific Considerations for Including Race and Ethnicity in ACT Analyses:

• Develop Questions & Methodological Strategies Informed by Conceptual Frameworks, e.g. Public Health Critical Race Methodology; National Institute of Minority Health and Health Disparities Research.

• In reporting of demographic data on race and ethnicity, ACT manuscripts should:
  - o state that ACT participants self-identified their race and ethnicity
  - o provide rationale for use of race as a key variable; if race is the **primary exposure** of interest or where analyses are **stratified by race** and/or **ethnicity**

• Analyses by Race and/or Ethnicity
  - Comparisons between race or ethnic groups should be informed by research questions.
  - Comparisons of race or ethnic groups to Non-Hispanic White participants is not required in ACT; this should only be done when supported by a research question
  - Within group analyses should acknowledge the heterogeneity within racial and ethnic groups.

• Data Interpretation & Reporting

o **Statistical power for race and ethnicity subgroup analyses**, should be sufficient to detect differences by that group. A**uthors** should acknowledge that sample selection limits interpretation of findings to the overall U.S. population or racial or ethnic subpopulations identified in the manuscript.
o Over time, the **ACT sample composition has been influenced by selective drop-out** that can be investigated through the use of inverse probability weighting and other methods.
o **Limitation:** Race and ethnicity are defined and interpreted within a socio-political framework as a proxy for both historical and ongoing differences in advantages arising from racism in social determinants of health, such as education, income, resilience and stressful life events. Other structural factors may be important for the data interpretation of racially disparate outcomes but are not available in ACT.

6. Acknowledgements

All ACT publications must include the following statement: "This research was funded by the National Institute on Aging (U19AG066567). Data collection for this work was additionally supported, in part, by prior funding from the National Institute on Aging (U01AG006781). All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of the National Institute on Aging or the National Institutes of Health. We thank the participants of the Adult Changes in Thought (ACT) study for the data they have provided and the many ACT investigators and staff who steward that data. You can learn more about ACT at: https://actagingstudy.org/."

The above acknowledgement text, along with resources for describing the ACT cohort and data in manuscripts can be found in the Manuscript Acknowledgement Guide.

7. Publication of Manuscripts and Presentations

After a manuscript is approved by the P&P Committee, the lead author is responsible for keeping ACT updated of the manuscript's status on an ongoing basis. The lead author must notify the P&P Committee when the manuscript is submitted to a journal and accepted for publication. Instructions for these notifications are included in the memo approving the manuscript. It is expected that authors will inform the P&P Committee of publication dates and send (1) a copy of the manuscript as accepted by the journal and (2) 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.

Investigators must agree that data reported in any document (manuscript, table, chart, study, report, etc.) will adhere to CMS' current cell size suppression policy; that is, no cell can have a cell count lower than 11. Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell less than 11.

8. Using ACT Data for Other Purposes

The P&P Committee must approve the following uses of ACT data:

Unpublished Data in Grant Applications or Contract Proposals

Investigators who seek to use ACT data that have not been previously published but are needed for grant applications or contract proposals must have prior approval for use by the P&P Committee. Proposals submitted to the P&P Committee will be reviewed and discussed during scheduled P&P Committee meetings.

Theses, Dissertations, and Academic Projects

All requests for use of ACT data by graduate students, medical students, residents and other trainees for theses or similar academic projects are to be reviewed by the P&P Committee. The student requesting use of ACT data must be associated with a sponsoring ACT investigator. 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 sponsor 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 sponsor, 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 sponsor, 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.

Use of 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.