Research and Publications SOP

Randomized Trial to Prevent Vascular Events in HIV — REPRIEVE (A5332)

A Multicenter Trial of the Advancing Clinical Therapeutics Globally for HIV/AIDS and Other Infections (ACTG) Network

Prepared by the REPRIEVE Executive Committee

Version 6.0

May 7, 2024

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General Principles

The REPRIEVE Executive Committee (EC) and Research and Publications Committee (RPC) are committed to maximizing the knowledge derived from the REPRIEVE trial by producing high-quality, high-impact publications in a timely and efficient manner. Each publication will exhibit scientific accuracy, integrity, originality, quality, and clarity. We provide a fair and transparent process that offers opportunity and support to investigators and study members wishing to participate in the development of publications and presentations resulting from REPRIEVE data.

General Considerations

- The responsibility and authority for REPRIEVE Research and Publications rests with the EC. The EC will delegate these functions to the REPRIEVE Research and Publications Committee (RPC) but retains final approval for all decisions, policies, and procedures.
- This document provides the overall REPRIEVE trial publication and presentation policies and is consistent with and satisfies the major goals of the ACTG Publications SOP. All authors should review the ACTG Publications SOP and adhere to the policies in that SOP.
- These policies are in effect for all REPRIEVE data sets held by the REPRIEVE trial investigators. Policies regarding any publicly available data sets containing REPRIEVE trial data are delineated below.
- These policies cover any document intended to disseminate results of analyses from REPRIEVE trial data or REPRIEVE-approved ancillary studies and include submissions to a scientific meeting, professional journal, periodical, book, or internet site.
- These policies and procedures will also cover the review, approval, and tracking of proposed and ongoing secondary analyses of imaging and biomarker repositories.
- These policies will remain in effect for 5 years after the REPRIEVE trial database is locked (November 13, 2028). After 5 years, consideration will be given to renewing this SOP.

General Policies and Standards

- Any proposal for publication involving data collected as part of the primary REPRIEVE trial or an approved ancillary objective/substudy of the REPRIEVE trial must be submitted by completing the REPRIEVE Proposal Template for Research and Publications (Appendix 1) to the RPC for approval in advance of any submission. A Request for Proposals (RFP) may be offered in collaboration with the ACTG Comorbidities Transformative Science Group (CTSG). These policies will refer to any RFP that may be offered through the ACTG CTSG.
- The final approval of authors and their position on the Masthead and overall responsibility for publication approval for any publication will be the REPRIEVE EC.
- For relevant studies, (e.g. those involving data from any ACTG sites vs. those involving data from only non-ACTG sites, such as the Canadian HIV Trials Network) the ACTG Publications Office will be made aware of the intent to publish, will receive a final draft prior to submission, and will also receive the final version following publication. A manuscript utilizing data only from non-ACTG sites (i.e. a Canadian HIV Trials Network specific manuscript) does not need to seek ACTG Publications Office approval.

- Writing Groups and the RPC will remain blinded until participant follow-up and data cleaning are completed, and the REPRIEVE clinical database is locked.
- All REPRIEVE data sets will be held by the Data Coordinating Center (DCC) and analyses performed by DCC statisticians unless otherwise approved. Baseline data will only be published before the end of the study if express permission to do so is granted by the REPRIEVE RPC and EC.
- Any proposal involving genome-wide association studies (GWAS) data must contain a section addressing NIH Policy NOT-OD-07-088 and related policies, including a statement in the proposal that only consented GWAS will be posted to dbGaP.
- All REPRIEVE publications must be submitted to PubMed Central (PMC) per contractual agreements and in compliance with the NIH Public Access Policy. The responsible party for submitting to PMC is the publisher/journal that has a formal agreement with PMC. If there is no formal agreement with the publisher/journal and PMC, or if the journal fails to submit, then the author or author's delegate is responsible for submitting to PMC.
- All relevant potential conflicts of interest must be disclosed at the time of appointment to a writing group and prior to publication or presentation.
- International Committee of Medical Journal Editors (ICMJE) guidelines should be followed for every manuscript submitted to a peer-reviewed journal.

Policies Related to Use of Biomarker Repository

- All proposals to access the imaging or biomarker repository collected as part of the primary REPRIEVE trial or an approved ancillary objective/substudy of the REPRIEVE trial must be submitted to the RPC for review and approval.
- It is expected that the REPRIEVE RPC that includes Lab Committee and/or the Imaging Core Laboratory will actively participate in such proposals.
- As with other proposals for publications, all REPRIEVE data sets will be held by the DCC and analyses performed by DCC statisticians unless otherwise approved.

Structural Overview

Communication regarding the research and publication process will be centralized through the REPRIEVE RPC for optimal coordination. The RPC will work closely with the EC to ensure timely and informed decision making.

Roles and Responsibilities

REPRIEVE Executive Committee

The REPRIEVE EC's role for publications is to ensure scientific accuracy, integrity, originality, quality, and clarity. The EC will ensure that all publications meet the overall quality standard prior to submission. The REPRIEVE EC will retain final decision-making authority for approval to prepare and

submit manuscripts, abstracts, presentations, or other works for publication or presentation according to this SOP and sponsor requirements.

The REPRIEVE EC consists of the Principal Investigators of the 2 National Heart, Lung, and Blood Institute (NHLBI) Grants that make up the REPRIEVE trial, the assigned NHLBI and NIAID Project Officers and the ACTG PI:

- REPRIEVE Clinical Coordinating Center (CCC) co-PIs– Steven Grinspoon MD and Pamela S. Douglas, MD and Project Manager, Katie Fitch, MSN, RPC Manager, Marissa Diggs, and, when needed, RPC Co-Chair, Markella Zanni, MD.
- REPRIEVE Data Coordinating Center (DCC) co-PIs – Michael Lu, MD, MPH and Heather Ribaudo, PhD, and Project Manager Kayla Paradis, BS
- NHLBI -Patrice Desvigne-Nickens, MD, Yves Rosenberg, MD, James Troendle, PhD, Patricia Bandettini, MD, Fassil Ketema, MS
- NIAID- Peter Kim, MD and Beverly Alston-Smith, MD
- ACTG PI- Judith Currier, MD

The REPRIEVE EC is responsible for publication policies and RPC oversight, overall dissemination plans, and reviewing and approving individual presentations and publications, as follows:

1. Publication policies and RPC oversight
    a. Approve overall RPC SOP and publication policies and priorities
    b. Appoint RPC Chair and members
    c. Adjudicate exceptions or exemptions to publications rules, charter, and processes with approval of the majority of EC members
    d. Approve authorship and other policies proposed by RPC

2. Overall dissemination plans
    a. Oversee overall dissemination plans of the REPRIEVE primary study and approved ancillary studies
    b. Avoid conflict with and/or duplication of other publications

3. Review and approve individual publications
    a. Review and approve final versions of all abstract and journal submissions.
    b. Review and, if needed, recommend adjustments to the choices for lead authorship, co-authorship, and manuscript scope to the RPC leadership and subsequent Writing Groups.
    c. Review and, if needed, recommend adjustments to the choices for appropriate meetings and peer-reviewed journal for publication and propose a list of alternative choices to the RPC leadership and subsequent Writing Groups.

Research and Publications Committee

The RPC's role is to:

1) identify presentations and publications to be written
2) set priorities

3) ensure high-quality and timely execution of these plans

All work should be performed in collaboration with the investigators and in consultation with the EC. To this end, the RPC will solicit, review, and approve ancillary studies and publication proposals, including funding mechanism and statistical analysis plan, and make determinations regarding priorities, authorship, and journal/meeting submission. Criteria for proposal approval will include significance, uniqueness, clarity of proposal and hypothesis, data and funding availability, and statistical approach including adequate power. The RPC is also responsible for prioritization of analyses and timely progress on approved proposals through active management of the review and submission process in a fair and transparent manner. Finally, the RPC will review and recommend for EC approval all abstracts, manuscripts, and presentations.

The RPC is also responsible for ensuring the inclusion of all interested and contributing authors as is feasible. Please see section below on authorship determination.

The REPRIEVE RPC will be limited to the voting members, including 1 physician chair (Steven Grinspoon, MD), and representatives from each of the CCC, DCC, NHLBI, NIAID, ACTG and Lab Committees, and REPRIEVE CAB. It is staffed by a publications manager and a senior staff statistician. RPC roles and responsibilities are delineated below:

1. **RPC Chair (Chair-Grinspoon, Co-Chairs Zanni, Douglas, Lu and Ribaudo)**
    a. Lead the development and implementation of a comprehensive, scientifically sound publication policy, authorship policy, and operational plan
    b. Provide oversight and leadership of the RPC including monitoring the progress of the development of each approved manuscript or presentation proposal to ensure publication/submission in a timely fashion
    c. Ensure that publication policy and planning reflect the needs and interests of the EC, the trial, and the REPRIEVE investigators
    d. Convene and chair regular RPC meetings
    e. Ensure that all RPC members and reviewers are performing their roles effectively
    f. If, in the opinion of the RPC, there is no member who has sufficient scientific background to review pertinent material, secure outside expert consultants to review the material

2. **Standing RPC Members include:** CCC PIs (Grinspoon/Douglas), DCC PIs (Lu/Ribaudo), ACTG Protocol Vice Chairs/Participating Members (Fichtenbaum, Zanni, Aberg, Malvestutto), REPRIEVE PM and Publications Manager (Fitch, M. Diggs), Cardiology Consultant (Bloomfield), ACTG Leaders (Currier), NIH Leaders (Desvigne-Nickens, Bandettini, Troendle, Alston-Smith), Kowa Leaders (Sponseller), Gilead Leaders (Rooney), ACTG CTS (Roa, Moran), Senior CBAR Statistician (Umbleja), REPRIEVE CAB members (Starr, A. Diggs). Additional investigators, including Principal Investigators of Ancillary Studies related to REPRIEVE, REPRIEVE Lab Committee Leaders, and CBAR statisticians, will be invited to join select RPC meetings as Ad Hoc Members.
    a. Commit adequate time to fulfill required responsibilities
    b. Report any conflicts of interest to RPC chair
    c. Assist the chair in formulating and executing the REPRIEVE publication policy, authorship

policy, and operational plan
d. Review, revise, and approve proposals to ensure the highest quality publications in a timely fashion (generally < 2 weeks from receipt of proposal)
e. Assist the chair in making suggestions for writing group members and reviewers (< 2 weeks)
f. Review and approve each abstract and manuscript submission including choice of journal (< 2 weeks from receipt of document)
g. Serve as a writing group liaison, reviewer, or manuscript coauthor as needed and as appropriate

3. RPC Publications Manager (Diggs and Designated Staff, including assistance of CTS)

a. Provide operational support or oversight for all aspects of RPC functions
b. Provide general communication and support regarding REPRIEVE publications and presentations
c. Distribute manuscript proposal form to potential authors; receive all publication requests
d. Collate and forward all documents to RPC and others as needed for meetings
e. Provide administrative management of internal manuscript review process, including requesting reviews and collating and returning reviewer comments to lead author
f. Arrange meetings/calls, set agenda in conjunction with chair, keep meeting summaries and action items, record key points of proposal and manuscript discussions.
g. Keep up-to-date RPC records including tracking status of all manuscript proposals, analyses, manuscript progress, journal submissions, responses, an up-to-date bibliography, and copies of all published manuscripts, presentations, and posters pertaining to the REPRIEVE trial
h. Help to enforce timelines of each step of publication process (including tracking and notification of relevant internal and external deadlines)
i. Ensure that NHLBI and ACTG approval procedures are followed
j. Tracking of journals submission and success rate
k. Ensure that all required publications are submitted to PubMed Central per contractual agreements and are in compliance with the NIH Public Access Policy. Information on submission procedures can be found at http://publicaccess.nih.gov/submit_process.htm.
l. Manage database of author and reviewer contact information and review and authorship involvement
m. Additional contributions (such as editing) on an ad hoc basis as commissioned
n. Coordinate dissemination of manuscript findings to REPRIEVE sites and participants, including participant summaries and REPRIEVE site calls to present findings.

4. Statistical RPC Members (Ribaudo and Designate)

a. Review and provide detailed comments on statistical aspects of proposals
b. Work with writing groups to finalize a detailed statistical analysis plan for each proposal, and ensure timely completion of statistical reviews
c. Ensure timely completion of all analyses, generally within 60 days of proposal approval
d. Lead statistical portions of presentations and manuscripts including methods, text, tables/figures, and reviewer responses

Writing Groups

Analogous to the ACTG Policy, Writing Groups will be formed for each publication. Each writing group will include at least 1 senior author/chair, 1 junior author/co-chair, 1 statistician, site/core lab investigator(s), 1 study co-PI, and 1 NIH representative, as appropriate (see Publication Categories section below for more detail). All manuscript writing groups should make an effort to provide training and publication opportunities by including a young investigator or fellow and providing guidance and support in the process. For additional information on authorship, please see the section Authorship Determination and Contributions.

1. **Lead Author/Chair/Co-chair Roles and Responsibilities**
    a. Report any conflicts of interest to RPC prior to accepting responsibility for manuscript authorship
    b. Determine funding, as required
    c. Complete proposal and determine analyses and data that are required for writing the manuscript, in conjunction with the study statistician
    d. Ensure production of the initial draft of the manuscript within 60 days of the availability of the data. In case of slow (or no) progress, the RPC may recommend to the EC that another writing group member be appointed chair
    e. Manage manuscript development process, including figure and table creation, maintaining version control, incorporating author and reviewer comments and edits, and monitoring author contributions
    f. Communicate status of the manuscript to writing group and RPC, and provide current version(s) as requested
    g. Ensure manuscript adheres to standards of excellence (described below) where appropriate
    h. Send manuscript to publications manager to submit to RPC for review process (generally completed within 2 weeks)
    i. Resubmit as needed until RPC, EC, ACTG Publications Office and NIH approval to submit for publication are provided
    j. Complete/submit a copyright and conflict of interest forms as required and provide instruction on submitting COIs to co-authors
    k. Submit approved manuscripts to the selected journal
    l. Keep writing group and RPC (via RPC Manager) apprised of abstract, journal review, and PMC submission status
    m. Assist in results dissemination through press releases, social media and other channels. For social media posts, include @REPRIEVETrial and/or #REPRIEVETrial when appropriate.
    n. Develop plain language summary of manuscript rationale and findings. The summary should be written in plain language and approximately 1-2 paragraphs in length, but no longer than 1 page. See examples on REPRIEVE website (www.reprievetrial.org) on the publications page.
    o. Share plain language summary with RPC Manager (mdiggs@mgh.harvard.edu) who will coordinate, with the CCC, approval and dissemination.

2. **Co- Author Roles and Responsibilities**
    a. Report any conflicts of interest to lead author and RPC prior to accepting responsibility for

manuscript authorship

b. Provide timely review and comments to lead author for detailed analysis plan and for each version
c. Provide all necessary information and documentation required for submission or publication, including conflict of interest statements and copyright transfer agreements
d. Provide sufficient effort toward manuscript development to warrant authorship and take public responsibility for appropriate portions of the content according to ICMJE criteria (see below and appendix)
e. The RPC, in consultation with the senior author, reserves the right to remove any author for inadequate or no participation

Guidelines for REPRIEVE Publications and Presentations

The highest standards of excellence in medical writing and communication should be the goal of authors publishing REPRIEVE results. All communications should be of interest to clinicians and investigators in cardiovascular disease and HIV medicine. In addition to the review system established for the critique of publications and presentations as described in the previous section, the following guidelines are suggested for maintaining the highest standards of excellence for REPRIEVE publications and presentations. **The required funding and acknowledgement statements are summarized in Appendix 7.**

1. All REPRIEVE publications must include the following acknowledgements of funding, see Appendix 7
2. In compliance with the NIH Grants Policy Statement**,** include the following disclaimer in all papers published, see Appendix 7.
3. An acknowledgements statement should be included in every manuscript and include the following statement, see Appendix 7.
4. The purpose of the report and the hypotheses tested (as appropriate) should be clearly stated in the introductory paragraphs.
5. Rationale for selection of the population inclusion/exclusion criteria should be explicitly delineated. Information should be presented on the loss of participants during the study including reasons for loss to follow-up (CONSORT Flow Diagram; http://www.consort-statement.org) or refer to a prior publication that does. Data on the comparability of the participants who participated in the trial and who constituted the study group should be included if relevant.
6. An “Ethics Statement” subsection should be included within the methods section, see Appendix 7.
7. Trial registration information with the US National Library of Medicine (http://www.clinicaltrials.gov) should be included (NCT02344290).
8. Reference the REPRIEVE Trial primary results papers (Grinspoon et al., NEJM, 2024 and Grinspoon et al., NEJM, 2023), REPRIEVE Mechanistic Substudy primary results paper (Lu et al., JAMA Cardiology, 2024) and/or the Supplemental Methods piece (Grinspoon et al, JID, 2020) as appropriate. These pieces cover overall data collection methods of the REPRIEVE

Trial and the primary results of the REPRIEVE Trial and the REPRIEVE Mechanistic Substudy. Methods not already described in an individual manuscript should be included.

9. The Methods section should provide sufficient information for the reader to critically understand the basic methods of the study and its major findings. Information about the statistical methods employed should be included, with assistance from the biostatistical resources available through CBAR.
10. Results, written in conjunction with CBAR statistician, should be reported in a concise fashion and their relevance to the hypotheses being tested should be clear. Pertinent results and the estimated range of treatment effects (e.g., confidence intervals) should be provided. Figures and tables should be used as appropriate to concisely provide information and should generally not duplicate data presented in the text.
11. Conflicts of interest should be reviewed by the authors at the time of submission and either stated in the manuscript or presentation or submitted separately to the journal, per journal policy.
12. Utilize the Lead Author/Writing Group Checklist (Appendix 5) during the writing and submission process to ensure all requirements are met.
13. See a list of common acronyms and terms in Appendix 6 to be used in REPRIEVE publications and ensure consistency across manuscripts.
14. Lead Authors/Writing Groups are strongly encouraged to publish Open Access to ensure accessibility of REPRIEVE findings to the community.

Manuscript Review Process and Procedures (See Flow Diagram Appendix 8)

1. Prior to drafting of the manuscript, after initial approval of the concept by the RPC and EC, the RPC manager will notify the ACTG Publications Office of intent to publish a manuscript and of the lead author(s) by email to ACTGPublications@mednet.ucla.edu. Please copy REPRIEVE CTS Laura Moran (Laura.Moran@dlhcorp.com) and Jhoanna Roa (jhoanna.roa@dlhcorp.com) on this email.

2. The statistical team at CBAR, working closely with the manuscript writing group, will complete all analyses for approved proposal, and summarize in statistical analysis report in approximately 60 days (depending on data availability).

3. Lead authors, in conjunction with core writing team and statistical lead(s), will complete first draft of manuscript in approximately 60 days. The lead author will then distribute the manuscript draft to all masthead authors, which may include REPRIEVE site investigators and collaborators, for comments and incorporate as appropriate.

4. After initial drafting of the manuscript, the lead author will determine author order and send the manuscript for review to the RPC by emailing Marissa Diggs at mdiggs@mgh.harvard.edu.

5. The RPC will review the manuscript and, if acceptable, will share the manuscript with the REPRIEVE EC who will provide feedback and approve author order. The RPC Manager will also distribute the manuscript with the Protocol Committee/Team, including Chairs and Vice-

Chairs, pharmaceutical collaborators, and relevant substudy teams, allowing 14 days for review.

6. Simultaneously, with committee/collaborator reviews, the RPC will submit the manuscript draft to the ACTG Publications Office (ACTGPublications@mednet.ucla.edu), copying the REPRIEVE CTS. The ACTG will log these in as pending papers for tracking purposes. The ACTG Publications Coordinator will confirm that the sites and grants have been appropriately acknowledged and will sign off for the network.

7. A final draft, incorporating suggestions from committees and collaborators as appropriate, will be approved by the RPC and EC. The RPC Manager will send the final copy to the ACTG Publications Office (email ACTGPublications@mednet.ucla.edu) and copy the REPRIEVE CTS. Any disputes over content, authorship or journal selection will be resolved by the REPRIEVE EC, which has representatives of REPRIEVE, NIH, and the ACTG. Upon submission to journal, RPC Publications Manager will notify NIH publications team. At time of revision request, CCC will discuss planned press/social media and communicate this with relevant collaborators (NIH, ACTG, MGH, etc.).

8. Once the manuscript has been accepted for publication, RPC Publications Manager will notify NIH, ACTG, writing group, and pharmaceutical collaborators, and send previous plain language summary examples to lead author and lead author will develop plain language summary of manuscript findings. This draft will be circulated internally within the CCC for edits. Once manuscript has been published, plain language summary will be shared on the REPRIEVE website and via REPRIEVE social media channels.

The Manuscript Review Process may be expedited for especially pertinent and time-sensitive findings (i.e. relating to COVID-19, etc.). Logistics regarding expedited manuscript review processes applicable to select manuscripts will be approved by the EC and relayed to lead/senior manuscript authors and entities/individuals required to review the manuscript prior to submission.

Authorship Determination and Contributions

Primary manuscripts: Named authors for the primary manuscripts will include the principal investigators, key protocol leadership, relevant investigators, NIH and biostatistical representatives, as detailed below. Masthead author order will be determined by the RPC, and approved by the EC. For select manuscripts, recognition for sites and site investigators will be provided by inclusion of authorship on behalf of ‘REPRIEVE Investigators’ and a list of participating study sites and investigators in an appendix to enable PubMed listing of these citations for these individuals.

Secondary manuscripts: Named authors for secondary manuscripts will include the principal investigators, key protocol leadership, relevant investigators, NIH and biostatistical representatives, as detailed below. The RPC will determine authorship and author order of manuscripts addressing secondary analyses or ancillary studies and will start this process by developing authorship policies and

procedures for EC approval. In doing so, the RPC will consider intellectual contribution to the conception, design, and writing of the study protocol, enrollment of participants, contributions to data quality (protocol compliance, missing data, etc.), service on committees, and other major contributions to the successful completion of the study (e.g., major role in statistical analysis, core lab functions). The EC will approve an overall approach to authorship developed by the RPC as well as review its proper implementation and adjudicate issues as required (see Authorship Determination).

The RPC is also responsible for ensuring the inclusion of all interested and contributing authors in the REPRIEVE publications process as is feasible. To this end, the RPC will invite contributing site investigators and co-investigators to participate as co-authors on manuscripts. An RFP may periodically be offered to investigators.

The RPC will track authorship and reviewer efforts in order to promote an equitable sharing of responsibility and credit. Site, core lab, and co-investigator responsibilities include responding to calls for authors, selecting manuscripts of greatest interest, and determining which member of their research team will be named on each manuscript to which the site/core lab is assigned.

Authorship Determination: The lead author will submit to the RPC a list of potential co-authors and author order based on contribution and/or planned contribution. All proposals must include at least one REPRIEVE Chair and Vice Chair (see protocol). This list is to be included on the REPRIEVE Proposal for Research and Publications (See Appendix 1). The RPC may then suggest additional co-authors based on contribution to the main trial, expertise, and equitable sharing of opportunities. The final list of authors and author order will be approved by the EC. Upon receiving final approval of the proposed author order, the lead author may then reach out to co-authors to notify them of their participation and position on the masthead for the proposed manuscript.

Authorship Contributions: In addition, each author must contribute the following:

a. Authorship credit should be based on 1) substantial contribution to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the manuscript or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet all conditions for 1, 2, and 3.
b. Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.
c. All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
d. Failure to participate sufficiently in the development of the manuscript or failure to provide required submission documentation may result in removal as an author.
e. Individuals who contribute significantly to the manuscript, but who do not meet authorship criteria should be named in the acknowledgements section.
f. All named authors are expected to meet the criteria for authorship as defined by the publishing journal, as well as to fully comply with the ethical obligations of authors as specified in the ICMJE Uniform Requirements for Manuscripts.
g. All authors will review and provide necessary critical comments and/or revisions of the manuscript prior to submission.

h. All authors will be expected to satisfy the responsibilities of authorship with respect to publication.

Publication Categories

Slightly different processes will be followed for primary manuscripts addressing pre-specified primary and secondary study aims and for those addressing secondary analyses and ancillary studies. However, regardless of the category, the lead author and writing group will be governed by the roles and responsibilities and authorship criteria outlined above.

Manuscripts Addressing Pre-Specified Primary and Secondary Study Aims (High Priority)

The EC will be responsible for identifying presentations and manuscripts that address the principal goals and objectives of the REPRIEVE trial and assigning a lead author to each. The lead /senior author will generally be the principal investigator overseeing the relevant study aim. Each lead author will follow the roles and responsibilities described in the Writing Groups section above.

Additional writing group authors for primary or secondary aim manuscripts will be recommended by the RPC and approved by the EC. Each manuscript should include (dependent upon direct involvement in the manuscript development process) at least one of the principal investigators and at least one senior biostatistician. Authorship will also include, as appropriate, representatives from the REPRIEVE enrolling sites, REPRIEVE co-investigators, and representatives from the core labs, as recommended by the RPC for inclusion based on interest, enrollment, data quality and completeness, other trial contributions, and interdisciplinary expertise. Each co-author will follow the roles and responsibilities of the writing group members and co-authors as described in the Writing Groups section above.

The EC is also responsible for determining the target meetings and journals and determining funding. As with all manuscripts, EC approval is required prior to submission.

Primary Manuscript Timeline

The primary REPRIEVE manuscript should be published approximately 12 months after the closed to follow-up date (CFU) or primary completion date (PCD) and should adhere to the timeline outlined in the table below. This timeline has been adapted from the ACTG 111 SOP: Publication Disclosure of Study Results-V13-080819.

Event	Timeframe	Responsible Party
Formation of writing team	~15 weeks prior to closed to follow-up date (CFU) or primary completion date (PCD)	Executive Committee (EC) with approval by RPC
Finalize primary Statistical Analysis Plain (SAP)	12 weeks prior to CFU/PCD	REPRIEVE statisticians
Completion of Primary Analysis Report	5-6 months after CFU/PCD	REPRIEVE statisticians

Draft of primary manuscript	60 days after receipt of primary analysis report	Writing team
Review of manuscript by masthead authors and REPRIEVE committees	~30 days	Writing team RPC Relevant committees

Manuscripts Addressing Secondary and Ancillary Study Results

Proposals for secondary and ancillary presentations and manuscripts may be made to the RPC by completing the manuscript proposal form and submitting it to the RPC. Before submitting a proposal, interested parties are encouraged to review the current list of manuscripts published or in development to assess potential for duplication, overlap, or conflict. The list may be obtained from the RPC publications manager. The RPC and ultimately the EC will determine the sequence and timing of when a proposal, if accepted, will move into the development/publication phase.

The RPC will review the proposal for required content; check for duplication, overlap, or conflict against the current list of approved proposals and manuscripts published or in development; and make recommendations for revision and/or approval. Areas of revisions may include scientific focus, overlap, lead authorship, and submission target. If adjudication is required, the RPC will forward the proposal to the EC for review. The RPC will also review identified funding for statistical support and manuscript development to ensure adequate support. Finally, the RPC and ultimately the EC will weigh in on the writing group and target meeting/journal proposed by the lead author and communicate these decisions to the proposal submitter as well as the EC.

After approval, each lead author and co-author will follow the appropriate roles and responsibilities as described in the Writing Groups section above.

Abstracts and Presentations

Abstracts and poster presentations that address the principal goals and objectives of the REPRIEVE trial will be managed by the RPC in a similar fashion, including assigning a lead author and co-authors. Abstracts must be submitted for approval as per the above process at least 5 days before submission to the conference, and presentation materials must be submitted at least 5 days prior to presentation. No presentations will be approved unless the related Research and Publications proposal has already been approved.

Authorship of abstracts will occur simultaneously with the analysis phase and will ideally include all members of the writing group for the approved related manuscript proposal.

Publicly Available Data Set

As REPRIEVE is a federally funded study, the REPRIEVE data set must be submitted to the study's NHLBI Program Officer no later than 3 years after the end of the clinical activity (final patient follow-up, etc.) or 2 years after the main paper of the trial has been published, whichever comes first (for more information see NIH Data Sharing Policy at: http://www.nhlbi.nih.gov/funding/datasharing.htm). With respect to REPRIEVE, it is anticipated that the main trial results will be included in a number of

publications which will set the timing for data sharing. Data are prepared by the study coordinating center and sent to the PO for review prior to release.

Although the REPRIEVE trial cannot control access to the data set once it has been publicly released as per NIH policy, the RPC will work closely and collaboratively as appropriate with potential authors to ensure that 1) the questions to be addressed are distinct from those already published or in progress, 2) data are properly interpreted in the context of the trial, and 3) the contributions of the original investigators are recognized.

Funding of Manuscripts

Costs of publication of the prespecified Primary and Secondary Aims, including page and illustration costs and licensing fees, will be covered by the REPRIEVE Clinical Coordinating Center. Publication costs for manuscripts related to key Aims of approved ancillary proposals will be funded by respective grants funding these projects. Because of the size and importance of the REPRIEVE trial it is anticipated that many manuscripts in addition to those describing the primary trial aims will result, and that the investigators will continue to publish after current NIH funding is exhausted. While current grants will fund the primary manuscripts and perhaps a small number of additional manuscripts, additional funds will be required to support statistical analyses required to publish secondary manuscripts consistent with NIH policy on secondary manuscripts PAR-13-009. These funds can come from investigators' research or discretionary accounts, new grant applications, industry collaborations or other unbiased source. Investigators are encouraged to plan in advance for such expenses.

Submission to Journal and Journal Acceptance

This process will follow the ACTG procedures as outlined in the ACTG Publications SOP, including ensuring submission to NIHMS, follow up with PubMed Central after acceptance, review of galleys, etc.

Press Releases

For any related press releases, the corresponding author will send a draft to the Publications Committee Co-Chair (Markella Zanni) for approval. The finalized version will then be sent to the EC, ACTG representatives, industry sponsors, and co-authors as a means of informing collaborators of content of press release.

Appendix 1: REPRIEVE Proposal Template for Research and Publications

The purpose of this form is to submit a proposal and analysis plan for consideration for approval by the REPRIEVE Research and Publications Committee (RPC). Investigators are strongly encouraged to contact a member of the RPC (Appendix 4) in advance of submitting a proposal to ensure that the topic is of interest to the trial, feasible with available data and does not overlap significantly with an already approved proposal(s). Investigators who are not affiliated with REPRIEVE and who are submitting a proposal may be asked to work with REPRIEVE-affiliated investigator(s) on the project.

Please complete this form and submit via e-mail to the REPRIEVE Publications Manager (mdiggs@mgh.harvard.edu). The completed proposal form will be reviewed by the RPC. The RPC meets at least monthly (typically the 3rd Monday of each month) and requires at least 2 weeks from proposal submission to review. **The proposal may not be longer than 5 pages.**

Administrative Information

Title		
Submitting author		
Senior author		
Name		
Address		
E-mail		
Phone		
Relationship to trial		
Date of proposal		If previously submitted, date of initial submission:
Funding source*		
Target meeting/ journal (w deadline, if any)		
Image core lab/ Biomarker approval (if applicable)	Enter name of approver/ date or NA	
Additional authors**	1.	
	2.	
	3.	
	4.	
	5.	

*Funding required to support statistical analyses
**Include all potential co-authors and propose order as anticipated to appear on the masthead

Overview of Proposed Study

Primary hypothesis or question	
Additional hypotheses or questions	
Proposal type (single ms, multiple ms, grant etc)	
Knowledge gap and importance	
Key references	

Brief description of methods including data sources

Data sources[#]	
Key inclusion/ exclusion criteria or patient subgroup	
Specific data elements and time points required to address the objective (see protocol and schedule of evaluations)	
Endpoints	
Strata or variables to be controlled for	
Modifiers of interest	
Statistical analysis plan (3-5 sentences)	

[#](i.e., REPRIEVE trial DCC, Biorepository, Image Repository, or approved ancillary objective/substudy)

Figure and tables listing (add rows as needed)

Tables	1.
	2.
	3.
Figures	1.
	2.

Appendix 2. REPRIEVE Proposal Scoring Sheet

Research and Publications Review Scoring Sheet
For internal RPC use only
Reviewers will be standing members of the RPC

OVERALL PRIORITY: Score 1–9 (1 is best score):

Score 1–9 for each category (1 is best score)

	Reviewer 1	**Reviewer 2**
Significance. Publishable as stand-alone paper		
Unique. Non-overlapping with prespecified analyses in primary paper or other approved proposals		
Rationale clearly laid out		
Question/hypothesis clearly stated		
Required data are available		
Power considered and justified		
Stats analysis approach appropriate		
Of interest regardless of outcome		
No practical barriers (e.g., funding, timelines)		
Authors are appropriate (if not, suggest others)		

GENERAL COMMENTS:

SPECIFIC COMMENTS:

Appendix 3. REPRIEVE Research and Publications Committee Review Form

Randomized Trial to Prevent Vascular Events in HIV

Research and Publications Review Form

For internal RPC use only

Review date	

Summary of review including any residual questions

Proposal significance	
Approach	
Analysis plan	
Funding	
Writing group membership	
Target journal/meeting	
Priority	
Need for EC review	

Statistical Analysis

Date assigned	
Target date for analysis results to go to author	

Appendix 4: REPRIEVE Research and Publications Committee Roster

Research and Publications Committee Roster

Chair: Steven Grinspoon, MD; Co-Chairs: Markella Zanni, MD, Pam Douglas, MD, Heather Ribaudo, PhD, and Michael Lu, MD
Publications manager: Marissa Diggs
REPRIEVE CTS: Jhoanna Roa, MD, Laura Moran, MPH
REPRIEVE Project Manager: Katie Fitch, MSN
Statistics staff: Heather Ribaudo, PhD, and Designates

Executive committee members or designees

- CCC and ACTG5332 PIs: Steven Grinspoon, MD, Pam Douglas MD
- DCC and ACTG5332 PIs: Heather Ribaudo, PhD, Michael Lu, MD
- NHLBI: Patrice Desvigne-Nickens, MD, Patricia Bandettini, MD, James Troendle, PhD
- NIAID: Beverly Alston-Smith, MD
- ACTG: Judy Currier, MD
- REPRIEVE CCC Project Manager: Katie Fitch, MSN

Other Members:

- REPRIEVE/A5332 Co-Investigators; Judy Aberg, MD, Carl Fichtenbaum, MD, Markella Zanni, MD, Gerald Bloomfield, Carlos Malvestutto, MD, Triin Umbleja, MS
- Industry Representatives: Craig Sponseller, MD, Jim Rooney, MD
- REPRIEVE CAB Members: Alicia Diggs and Kate Starr

Appendix 5: Lead Author/Writing Group Checklist

The purpose of this checklist is to make the lead author/writing group aware of tasks to be completed prior to publication of a manuscript and to track the progress of the manuscript.

Please complete this checklist up to the Review Stage. Then, submit this checklist to the REPRIEVE Publications Manager (mdiggs@mgh.harvard.edu) along with the manuscript draft. This checklist will be filed and updated as needed by the RPC manager.

Manuscript Title: _____
Lead Author/Writing Group: _____

Task	Completed ☑
Proposal Stage	
Author(s) has submitted completed proposal form (Appendix 1 of Publications SOP) to Research and Publications Committee (RPC) manager, Marissa Diggs (mdiggs@mgh.harvard.edu), for approval process.	☐
RPC manager has notified the ACTG Publications Office and NIH of intent to publish.	☐
Author(s) has conferred with statistician to develop formal written analysis plan.	☐
Writing Stage	
Author(s) has cited the REPRIEVE study primary results manuscripts, REPRIEVE mechanistic substudy primary results manuscript, and/or the JID supplement as appropriate and reviewed other REPRIEVE publications that may be relevant to the present manuscript. Final REPRIEVE Primary Results: Grinspoon et al., NEJM, 2024 REPRIEVE Primary Results: Grinspoon et al., NEJM, 2023 REPRIEVE Mechanistic Substudy Results: Lu et al., JAMA Cardiology, 2024 JID Supplement: Grinspoon et al., JID, 2020	☐
Author(s) has ensured that manuscript follows authorship policies (See Authorship Determination and Contributions) and any assigned site investigator authors have been included as Masthead Authors. Please reach out to the REPRIEVE Publications Manager, Marissa Diggs (mdiggs@mgh.harvard.edu), for assistance with site investigator assignment.	☐
Author(s) has ensured MS includes the required acknowledgement of funding and disclaimer in Appendix 7 (see Publications SOP, Guidelines for REPRIEVE Publications and Presentations) and cited any other applicable grants, including any R01, T32, F32, or K funding.	☐
Author(s) has ensured terms and acronyms are consistent with Appendix 6	☐
Author(s) included Clinical Trials Registration number: NCT02344290	☐
Author(s) included Ethics and Acknowledgement Statements in Appendix 7	☐
Author(s) included conflicts of interest and disclosures as required by the target journal	☐
Review Stage	
Ensure all Masthead Authors have reviewed the MS	☐

Author(s) share draft of manuscript and Lead Author/Writing Group Checklist with REPRIEVE Publications Manager (mdiggs@mgh.harvard.edu)	☐
RPC manager has distributed draft of manuscript to REPRIEVE committees (RPC, EC, Protocol Committee), Pharmaceutical Collaborators, and ACTG Publications Office for review	☐
RPC manager has run manuscript text (except methods) through Ithenticate	☐
Author(s) make necessary revisions to MS from RPC/EC/Protocol Committee, Pharmaceutical Collaborators, and ACTG Publications Office reviews to manuscript	☐
Author(s) send final MS to RPC (mdiggs@mgh.harvard.edu) for approval	☐
Submission and Acceptance	
Author(s) submit MS for publication and send final submitted version to RPC manager (mdiggs@mgh.harvard.edu)	☐
RPC manager sends submitted version of MS to ACTG Publications Office and NIH	☐
Develop plain language summaries	☐
Author(s) sent comments/responses from Journal to RPC (mdiggs@mgh.harvard.edu)	☐
Author(s) make necessary final edits to MS and address comments in a timely manner	☐
Author(s) submit revised MS to journal	☐
Author(s) review galley proofs in timely manner	☐
Complete necessary post acceptance responsibilities, eg related to PubMed, ClinTrials, and Journal requirements	☐

*RPC will send to the RPC/EC/Protocol Committee/Team (includes pharmaceutical representatives) and ACTG Publications Office for review

Checklist completed by:

Date:

Appendix 6: List of Common Terms and Acronyms

For consistency across REPRIEVE associated publications, we recommend using the acronyms and terms provided in the table below. Additionally, we recommend authors reference the NIAID Language Guide while writing manuscripts relating to REPRIEVE. The language guide can be found here: https://www.hptn.org/resources/HIVLanguageGuide

Term	Acronym
Health and Healthcare Related Terms	
Cardiovascular disease	CVD
People with HIV	PWH
People Living with HIV	PLWH
Major adverse cardiovascular events	MACE
Atherosclerotic cardiovascular disease	ASCVD
Antiretroviral therapy	ART
Myocardial infarction	MI
Primary Care Provider	PCP
Organizations, Studies, and Committees	
The Randomized Trial to Prevent Vascular Events in HIV	REPRIEVE
Pitavastatin to Reduce Physical Function Impairment and Frailty in HIV	PREPARE
Clinical Coordinating Center	CCC
Data Coordinating Center	DCC
National Heart, Lung, and Blood Institute	NHLBI
National Institute of Allergy and Infectious Diseases	NIAID
Division of AIDS	DAIDS
Advancing Clinical Therapeutics Globally for HIV/AIDS and Other Infections	ACTG
National Institutes of Health	NIH
Institutional Review Board	IRB
Clinical Events Committee	CEC
Executive Committee	EC
Clinical Research Site	CRS
Site Selection and Performance Committee	SSPC
Suggested Common Terms	
Use “pitavastatin calcium”	
Use “natal sex”	
Participants had “low to moderate traditional ASCVD risk”	
Enrollment took place between “March 2015 and July 2019”	
“Over 100 clinical sites enrolled”	
12 countries participated	
Kowa Pharmaceuticals America, Inc.	
Gilead Sciences, Inc.	

Appendix 7: Funding and Acknowledgement Statements

Funding statement

This study is supported through NIH grants U01HL123336 and 1UG3HL164285, to the Clinical Coordinating Center, U01HL123339 and 1U24HL164284, to the Data Coordinating Center, and P30DK040561 to the Nutrition Obesity Research Center at Harvard (NORCH) as well as funding from Kowa Pharmaceuticals America, Inc., Gilead Sciences, and ViiV Healthcare. The NIAID supported this study through grants UM1 AI068636, which supports the ACTG Leadership and Operations Center; and UM1 AI106701, which supports the ACTG Laboratory Center.

NHLBI/NIH Grants Policy Statement

The views expressed in this manuscript are those of the authors and do not necessarily represent the views of the National Heart, Lung, and Blood Institute or the National Institute of Allergy and Infectious Diseases; the National Institutes of Health; or the U.S. Department of Health and Human Services.

Acknowledgements Statement

The study investigators thank the study participants, site staff, and study-associated personnel for their ongoing participation in the trial. In addition, we thank the following: the ACTG for clinical site support; ACTG Clinical Trials Specialists (Laura Moran, MPH, and Jhoanna Roa, MD) for regulatory support; the data management center, Frontier Science Foundation, for data support; the Center for Biostatistics in AIDS Research for statistical support; and the Community Advisory Board for input for the community.

IRB/Ethics Statement (to be included in Methods section of MS, in subsection titled “Ethics Statement”)

Each clinical research site obtained institutional review board (IRB)/ethics committee (EC) approval and any other applicable regulatory entity (RE) approvals. Participants were provided with study information, including discussion of risks and benefits and signed the approved declaration of informed consent.

Appendix 8: Manuscript/Abstract Review Process and Procedures Flow Diagram