1.0 PURPOSE

This document states the requirements for the publication, presentation, and disclosure of any work conducted by the AIDS Clinical Trials Group (ACTG) Network, or governed by subcontract agreements executed by University of California, Los Angeles (UCLA) on behalf of the ACTG.

2.0 SCOPE

This SOP applies to all ACTG-related publications including manuscripts, abstracts, Clinical Trials Unit (CTU)/Clinical Research Site (CRS) Scientific and Participant Summaries, and press releases.

It is the policy of the ACTG to publish and share research results in a timely manner in accordance with the National Institutes of Health (NIH) Public Access Policy http://publicaccess.nih.gov/policy.htm. It is also the policy of the ACTG to publish the results of the main study/project primary manuscript prior to those of substudies and secondary manuscripts, unless otherwise approved by the Scientific Agenda Steering Committee (SASC). This policy is expected to be followed for ACTG studies, collaborative studies with cosponsoring agencies or other clinical trials networks, and studies in which data are collected and analyzed by a network or group other than the ACTG Statistical and Data Management Center (SDMC), unless alternative policies are mutually agreed upon and codified in the Clinical Trials Agreement (CTA), Letter of Understanding (LOU), or Memorandum of Understanding (MOU), or otherwise approved by the ACTG Executive Committee (AEC), Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), or the AEC, with DAIDS/NIAID approval, have authority to embargo any/all information in CTU/CRS Scientific Summaries, Participant Summaries, and press releases, until information is made public (i.e., abstract presentation or manuscript publication).

3.0 REPORTING SEX AND GENDER

All presentations of studies (oral, written, poster, and other) must include sex and gender in the reported demographics of study participants. If the information is not available, the presentation should state so explicitly.

4.0 DEFINITIONS

4.1 Writing Team: A subgroup of the protocol team members who collaborate to write an abstract or manuscript summarizing results of the study protocol. Occasionally, specialists who are not protocol team members may be included.

4.2 Masthead authors: The group that is listed as authors on the manuscript or abstract.

4.3 Scientific Committee (SC): Committee responsible for reviewing manuscript or abstract prior to journal or conference submission, includes Transformative Scientific Groups (TSGs), Collaborative Science Groups (CSGs) and SASC.

4.4 Designated committee reviewer: SC member assigned to review the manuscript or abstract prior to journal or conference submission if the Scientific Committee chair and vice chair have conflicts.
4.5 **Primary manuscript:** Manuscript that reports results of analyses of the primary and secondary outcome measures summarized in the Primary Analysis Report.

4.6 **Secondary manuscript:** Manuscript that reports results of analyses not specified in the primary Statistical Analysis Plan, e.g., baseline data reports, other outcome measures included in the protocol, newly planned analyses, cross-protocol data, or analysis of specimens collected as part of a clinical trial, but used for analyses not previously specified in the protocol.

4.7 **New Work Concept Sheet (NWCS):** Study that reports results of analysis of specimens from existing ACTG protocol(s) that were not specified in the ACTG protocol(s) or defined as a secondary analysis within 60 days of receipt of the final analysis by the writing team chair. (See SOP ACTG-109, “NWCS Development and Review”.)

4.8 **Data Analysis Concept Sheet (DACS):** Study that reports results of analysis of data from one or more existing ACTG studies that were not specified in the ACTG protocol(s) or defined as a secondary analysis for that ACTG protocol within 60 days after receipt of the final analysis by the writing team chair. (See SOP ACTG-106, “DACS Development and Review”.)

4.9 **Non-Protocol related abstract or manuscript:** An abstract or manuscript that is not affiliated to an ACTG protocol that contains ACTG-related data (e.g., related to committee, site or laboratory, ACTG policies, process, or procedure-related).

4.10 **Abstract:** Brief report of ACTG-related data, prepared for submission to a conference. May be classified as a regular abstract or a late-breaker abstract.

4.11 **Protocol team:** Group of team members that appear in the protocol roster, which usually includes pharmaceutical/industry representatives and other funders of the study.

4.12 **CTU/CRS scientific summary:** Limited scientific summary of the study results; disseminated to ACTG CTUs and CRSs prior to public presentation or publication of the results.

4.13 **Participant summary:** Summary for study participants describing the study results and implications of them. To be distributed with CTU/CRS scientific summary.

4.14 **National Institutes of Health Manuscript Submission System (NIHMS):** An online system for submitting and managing final, peer-reviewed manuscripts in accordance with the NIH Public Access Policy.

4.15 **PubMed Central (PMC):** The National Institute of Health (NIH) digital archive of full-text, peer-reviewed journal articles; its content is publicly accessible and integrated with other databases (See [http://www.pubmedcentral.nih.gov/](http://www.pubmedcentral.nih.gov/)).

4.16 **Publication costs:** The author fees associated with publishing peer-reviewed manuscripts.

4.17 **Primary Completion Date:** The date the final participant in a clinical study was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether or not the trial was concluded according to the pre-specified protocol or was terminated, or participant visits continue for collection of data for secondary outcomes.
## 5.0 RESPONSIBILITIES AND PROCEDURES

### 5.1 ACTG Manuscripts

**Primary Manuscript(s) of Protocols**

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<th>EVENT</th>
<th>PRIMARY MANUSCRIPT TIMELINE</th>
<th>PROCEDURES</th>
<th>RESPONSIBLE PARTY(IES)</th>
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| Formation of writing team | ~ 15 weeks prior to closed to follow-up date (CFU) or primary completion date (PCD) | • Form writing team.  
• Notify ACTG Publications Office and committee leadership of writing team members (see Appendix 1: Writing Team Guidelines, Writing Team Membership section).  
• Review writing team membership; if necessary make recommendations. | Protocol team  
Protocol Chair/Writing Chair and/or CTS  
SC Chair/Committee Leadership |
| Final revisions to the primary Statistical Analysis Plan | 12 weeks prior to CFU/PCD | • Finalize primary Statistical Analysis Plan. (See SOP ACTG-101, “Study Closure”.) | Protocol Chair(s) and Protocol Statistician(s) |
| Determination of summaries | Near finalization of primary Statistical Analysis Plan | • Determine a need for CTU/CRS Scientific Summaries based on the primary Statistical Analysis Plan, or a preliminary analysis prior to preparation of full primary analysis report (see table for CTU/CRS Scientific Summaries). | SC Chair, in consultation with DAIDS, SASC, Protocol Chair(s), and Protocol Statistician(s) |
| Completion of Primary Analysis Report | 5-6 months after CFU/PCD  
*Note: This timeline may be adjusted by the SC (e.g., to accommodate studies with outcome measures requiring additional time to ascertain)* | • Send finalized Primary Analysis Report to protocol chair(s), ACTG network chair/vice chair and SC chair/vice chair.  
• Notify ACTG Publications Office and the CTS that the Primary Analysis Report has been sent. | Protocol Statistician(s) |
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| 60-Day preparation of manuscript | Upon receipt of the Primary Analysis Report | • Oversee timely completion of manuscript and adherence to timelines.  
• Ensure that the journal’s requirements are read and understood prior to any submission of a manuscript. If there are questions regarding special requirements/situations that are unfamiliar, the writing chair should consult with the ACTG Publications Office prior to submission of the manuscript. Questions regarding author’s rights should be directed to the author’s institution.  
• Determine number and order of masthead authors; acknowledge ACTG support in the manuscript. When possible, journals should be chosen that do not limit the number of masthead authors. (See Appendix 1: Writing Team Guidelines, Acknowledgement section.)  
• Contact ACTG Publications Office to solicit names and grant numbers of participating sites.  
• If there will be a delay in the submission of the manuscript for ACTG review, an extension request should be submitted (See Appendix 2: Requesting a Manuscript Writing Extension). | Committee Leadership/ Writing Team Chair  
Writing Team Chair |
| 30-Day team review of manuscript by masthead authors, writing team, and protocol team to include DAIDS, SDAC, and the pharmaceutical and biomedical representatives | Following 60-day writing period | • Send manuscript for 14-day review and sign-off (see Appendix 3: Distribution Lists for 14-day review distribution list). Pharmaceutical and biomedical industry representatives are allowed up to 30 days for review, unless otherwise specified in the CTA. **NOTE:** It is the Writing Team’s responsibility to ensure that all of the pharmaceutical/industry reps have been allowed adequate time to review the manuscript.  
• If not already addressed in the CTA, request that the pharmaceutical company provide a statement indicating their... | Writing Team Chair |
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| Submission of manuscript for ACTG review following team review | 90 days after the final Primary Analysis Report is received by protocol chair(s) | • Submit manuscript to ACTG Publications Office, via Submission Central on the ACTG member website https://member.actgnetwork.org/pub/cs/review, after final team review.  
  - If submitting to an Open Access journal, notify the ACTG Publications Office for determination of Open Access fee coverage (see Appendix 6: ACTG Publication Costs). | Writing Team Chair |
| ACTG review of manuscript | Within 10 business days after manuscript is received from Writing Team | • Send manuscript to SC chair/vice chair/designated committee reviewer for approval/disapproval.  
  • Send manuscript to additional review parties for review concurrent with committee review. (See Appendix 3: Distribution Lists for ACTG Publications Office manuscript review distribution list.)  
  • Acquire list of masthead authors with significant financial interests, or a statement that none of them do, from the ACTG Financial Disclosure Coordinator (FDC). (See SOP ACTG-107, “ACTG Network-Specific Financial Disclosure and Conflict of Interest Procedures”.)  
  • Review manuscript and submit any comments to ACTG Publications Office.  
  | ACTG Publications Office  
  Financial Disclosure Coordinator  
  Additional review parties |
| Completion of ACTG review | Within 10 business days after manuscript is received from ACTG Publications | • Review manuscript and return manuscript endorsement sheet to ACTG Publications Office. (See Appendix 4: Committee Reviewer Responsibilities.)  
  • Send endorsement response and additional review party | SC Chair/Vice-Chair/designated reviewer  
  ACTG Publications |
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|       | Office comments to corresponding author. | • Respond to review comments (via options below)  
  o Approved [and reviewer does not want to see MS again]: proceed with submission to journal.  
  o Approved and reviewer wants to see manuscript again prior to submission: incorporate comments and send revised manuscript and responses to ACTG Publications Office within 20 days.  
  o Disapproved: resubmit revised manuscript to ACTG Publications Office within 60 days for 10 day ACTG Review as indicated above.  
  • **NOTE:** Substantial changes following ACTG review must be agreed on by the masthead authors and SC chair/vice chair/designated committee reviewer. If agreement cannot be reached, refer to the SASC chair for resolution. | Writing Team Chair |
| Revision and resubmission of manuscript 60 days after acceptance with revisions or rejection | Within 60 days of rejection following initial ACTG review | • Distribute revised manuscript, review comments, and responses to writing team, masthead authors, and protocol team to include SDAC, DAIDS, and the pharmaceutical representatives for a second team review.  
  • Resubmit revised manuscript to ACTG Publications Office, via Submission Central on the ACTG member website, for a second ACTG review prior to journal submission.  
  o Failure to submit for a second ACTG review within 60 days may result in sanctions, as described in Appendix 5: Sanctions.  
  • Send manuscript for second 10-day ACTG review to SC Chair/Vice-Chair/designated reviewer. | Writing Team Chair  
  ACTG Publications Office |
- Respond to second review comments via options listed in “Completion of ACTG Review” section above.

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| Submission to journal     | Within 30 days after ACTG approval | - Ensure masthead authors’ disclosure of potential conflicts of interest as required by journal policy.  
- Prior to signing the journal publication agreement (or similar copyright transfer agreement)-  
  o Ensure the publishing agreement allows the paper to be posted to PubMed Central, in accordance with NIH Public Access Policy.  
  o Contact the ACTG Publications Office for assistance in retaining author rights for compliance to Public Access Policy.  
- At the time of journal submission, the journal must be notified that the manuscript was funded wholly or in part by NIH.  
- If a journal requests a statement about access to data, use the following statement: "The authors confirm that all data underlying the findings are fully available without restriction. Due to ethical restrictions, study data are available upon request from sdac.data@sdac.harvard.edu with the written agreement of the AIDS Clinical Trials Group."  
- If a journal requests a statement about access to data and statistical analysis programs, use the following statement: "The authors confirm that all data and statistical programming code underlying the findings are fully available upon request from sdac.data@sdac.harvard.edu with the written agreement of the AIDS Clinical Trials Group." | Writing Team Chair |

Writing Team Chair
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| Journal acceptance for publication | Following notification of acceptance for publication | • Awardees are responsible for ensuring manuscripts are submitted to the National Institutes of Health Manuscript Submission site (NIHMS) upon acceptance for publication. If the manuscript is being published in a journal that does not deposit final published articles in PubMed Central, submit a request with the final peer reviewed version (e.g., Microsoft Word document), all tables, figures, and supplementary information, and a copy of the signed publication agreement (or similar copyright transfer agreement) to PubMed Central via NIHMS. Add the ACTG Network Grant number to the NIHMS at the time of submission. The ACTG Publications Office at the Leadership and Operations Center (LOC) at ACTGPublications@partners.org can be contacted with questions. The Leadership and Operations Center can submit the manuscript on behalf of the corresponding author as a last resort.  

- Approve the release and PubMed Central formatting of your manuscript when receiving the email notification from NIHMS.³  

- If the masthead authors are responsible for publication fees, see Appendix 6: ACTG Publication Costs. | Writing Team Chair or senior author |
<p>| Assignment of scientific contribution credit | Within 30 days after publication | • Obtain an electronic copy of the published manuscript and, if appropriate, assign scientific contribution credit for the annual site and laboratory performance evaluations in accordance with SOP ACTG-126, “ACTG Performance Measures and Standards”. | Network Coordinating Center |</p>
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<th>EVENT</th>
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| Formation of the writing team | Timeline will vary | • Form writing team.  
• Notify ACTG Publications Office and committee leadership of writing team members (see Appendix 1: Writing Team Guidelines, Writing Team Membership section).  
• Review writing team membership; if necessary make recommendations. | Protocol Team  
Protocol Chair(s)/Writing Team Chair and/or CTS  
SC Chair/Committee Leadership |
| Preparation of Statistical Analysis Plan for baseline or secondary manuscripts | Timeline will vary | • Define Statistical Analysis Plan prior to initiation of data analysis. (See SOP ACTG-101, “Study Closure”)  
  o Analyses using non-Statistical and Data Analysis Center (SDAC) statistical expertise must follow SOP ACTG-158, “Requests for Data from ACTG Studies”, for the procedure for conduct of secondary analyses when SDAC resources are not available. | Protocol Chair(s) and Protocol Statistician(s) |
| Completion of analysis report | Timeline will vary | • Send finalized analysis report to protocol chair(s), ACTG network chair/vice chair, and SC chair/vice chair.  
• Notify ACTG Publications Office and the CTS that analysis report has been sent. | Protocol Statistician(s) |
<p>| 60-Day preparation of manuscript | Upon receipt of the finalized analysis | • Oversee timely completion of manuscript and adherence to timelines. | Committee Leadership/ Writing Team Chair |</p>
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|       | report                                 | - Ensure that the journal’s requirements are read and understood prior to any submission of a manuscript. If there are questions regarding special requirements/situations that are unfamiliar, the Writing Team chair should consult with the ACTG Publications Office prior to submission of the manuscript. Questions regarding author’s rights should be directed to the author’s institution.  
- Determine number and order of masthead authors; acknowledge ACTG support in the manuscript. When possible, journals should be chosen that do not limit the number of masthead authors (see Appendix 1: Writing Team Guidelines, Acknowledgements section).  
- Contact ACTG Publications Office to solicit names and grant numbers of participating sites (only for major secondary manuscripts).  
- Finalize manuscript within 60 days from date the analysis report was received by the protocol chair(s).  
- If there will be a delay in the submission of the manuscript for ACTG review, an extension request should be submitted (see Appendix 2: Requesting a Manuscript Writing Extension). | Writing Team Chair |
| 30-day team review of manuscript by masthead authors, writing team, and protocol team to include DAIDS, SDAC, and the pharmaceutical and biomedical representatives | Following 60-day writing period | - Send manuscript for 14-day review and sign-off (see Appendix 3: Distribution Lists for 14-day review distribution list). Pharmaceutical and biomedical industry representatives are allowed up to 30 days for review, unless otherwise specified in the CTA.  
*NOTE: It is the Writing Team's responsibility to ensure that all of the pharmaceutical/industry reps have been allowed adequate time to review the manuscript.* | Writing Team Chair |
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| ACTG review of manuscript | Within 10 business days after manuscript is received from Writing Team | • Send manuscript to SC chair/vice chair/designated committee reviewer for approval/disapproval  
• Send manuscript to additional review parties for review concurrent with committee review. (See Appendix 3: Distribution Lists for ACTG Publications Office manuscript review distribution list)²  
• Acquire list of masthead authors with significant financial interests, or a statement that none of them do, from the ACTG Financial Disclosure Coordinator (FDC). (See SOP ACTG-107, “ACTG Network-Specific Financial Disclosure and Conflict of Interest Procedures”.)  
• Review manuscript and submit any comments to ACTG Publications Office.² | ACTG Publications Office  
Financial Disclosure Coordinator  
Additional review parties |
| Submission of manuscript for ACTG review following team review | 90 days after the analysis report is received by protocol chair(s) | • If not already addressed in the CTA, request that the pharmaceutical company provide a statement indicating their willingness to share the study’s protocol with the public at the journal’s request.  
• Submit manuscript to ACTG Publications Office, via Submission Central on the ACTG member website https://member.actgnetwork.org/pub/cs/review, after final team review.  
• If submitting to an Open Access journal, notify the ACTG Publications Office for determination of Open Access fee coverage (see Appendix 6: ACTG Publication Costs). | Writing Team Chair |
| Completion of ACTG review | Within 10 business days after manuscript is received from ACTG Publications Office | • Review manuscript and return manuscript endorsement sheet to ACTG Publications Office (see Appendix 4: Committee Reviewer Responsibilities).  
• Send endorsement response and additional review party | SC Chair/Vice-Chair/designated reviewer  
ACTG Publications Office |
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<td>comments to corresponding author.</td>
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<td>Writing Team Chair</td>
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<td>• Respond to review comments (via options below)</td>
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<td>▪ Approved [and reviewer does not want to see MS again]: proceed with submission to journal.</td>
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<td></td>
<td>▪ Approved and reviewer wants to see manuscript again prior to submission: incorporate comments and send revised manuscript and responses to ACTG Publications Office within 20 days.</td>
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<td>▪ Disapproved: resubmit revised manuscript* to ACTG Publications Office within 60 days for 10 day ACTG Review as indicated above.</td>
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<td><strong>NOTE:</strong> Substantial changes following ACTG review must be agreed on by the masthead authors and SC chair/vice chair/designated committee reviewer. If agreement cannot be reached, refer to the SASC chair for resolution.</td>
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<td>Revision and resubmission of manuscript 60 days after acceptance with revisions or rejection</td>
<td>Within 60 days of rejection following initial ACTG review</td>
<td>• Distribute revised manuscript, review comments, and responses to writing team, masthead authors, and protocol team to include SDAC, DAIDS, and the pharmaceutical representatives for a 2nd team review.</td>
<td>Writing Team Chair</td>
</tr>
<tr>
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<td>• Resubmit revised manuscript to ACTG Publications Office, via Submission Central on the ACTG member website, for a second ACTG review prior to journal submission.</td>
<td>Writing Team Chair</td>
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<td>▪ Failure to submit for a 2nd ACTG review within 60 days may result in sanctions, as described in Appendix 5: Sanctions.</td>
<td>ACTG Publications Office</td>
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<td>• Send manuscript for second 10-day ACTG review to SC Chair/Vice-Chair/designated reviewer.</td>
<td>Writing Team Chair</td>
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<td>• Respond to second review comments via options listed in “Completion of ACTG review” section above.</td>
<td>Writing Team Chair</td>
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| Submission to journal         | Within 30 days after ACTG approval     | • Ensure masthead authors’ disclosure of potential conflicts of interest as required by journal policy.  
• Prior to signing the journal publication agreement (or similar copyright transfer agreement)-  
  o Ensure the publishing agreement allows the paper to be posted to PubMed Central, in accordance with NIH Public Access Policy.  
  o Contact the ACTG Publications Office for assistance in retaining author rights for compliance to Public Access Policy.  
• If a journal requests a statement about access to data, use the following statement: “The authors confirm that all data underlying the findings are fully available upon request from sdac.data@sdac.harvard.edu with the written agreement of the AIDS Clinical Trials Group.”  
• If a journal requests at statement about access to data and statistical analysis programs, use the following statement: “The authors confirm that all data and statistical programming code underlying the findings are fully available upon request from sdac.data@sdac.harvard.edu with the written agreement of the AIDS Clinical Trials Group.”  
• At the time of journal submission, the journal must be notified that the manuscript was funded wholly or in part by NIH.  
• Submit journal review updates and decisions to ACTG Publications Office within 10 days after receipt.  
• Maintain copies of journal review comments (to be made available to SASC or SC upon request). | Writing Team Chair |
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| Journal acceptance for publication                  | Following notification of acceptance for publication | • If the manuscript is being published in a journal that does not deposit final published articles in PubMed Central, submit a request with the final peer reviewed version (e.g., Microsoft Word document), all tables, figures, and supplementary information, and a copy of the signed publication agreement (or similar copyright transfer agreement) to PubMed Central via NIHMS. Add the ACTG Network Grant number into the NIHMS at the time of submission. The ACTG Leadership and Operations Center at ACTGPublishations@partners.org can be contacted with questions. The Leadership and Operations Center can submit the manuscript on behalf of the corresponding author as a last resort.  
• Approve the release and PubMed Central formatting of your manuscript when receiving the email notification from NIHMS.  
**NOTE:** If the masthead authors are responsible for publication fees, see Appendix 6: ACTG Publication Costs. | Writing Team Chair or senior author |
| Assignment of scientific contribution credit         | Within 30 days after publication        | • Obtain an electronic copy of the published manuscript and, if appropriate, assign scientific contribution credit for the annual site and laboratory performance evaluations in accordance with SOP ACTG-126, “ACTG Performance Measures and Standards”. | Network Coordinating Center  |
| Referencing ACTG published manuscripts              | Following publication of manuscript online or in journal | • When submitting an application, proposal, or report to the NIH, the PubMed Central reference number (PMCID) must be included when citing ACTG papers that arise from NIH-funded research. | ACTG members                 |
## NWCS/DACS Manuscripts

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<th>EVENT</th>
<th>NWCS/DACS MANUSCRIPT TIMELINE</th>
<th>PROCEDURES</th>
<th>RESPONSIBLE PARTY(IES)</th>
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<tr>
<td>NWCS/DACS request for use of study data for NWCS or DACS</td>
<td>One year after publication of primary manuscript(s) from the parent protocol(s) and team confirmation of secondary analyses to be completed and published by the parent protocol team(s)</td>
<td>• Once the study data are openly available for use by investigators outside the protocol team, circulate NWCS and/or DACS as a courtesy to the parent protocol team(s), and if samples are to be used, ascertain whether or not sufficient samples are available for proposed work.</td>
<td>Protocol/Non-protocol Investigators</td>
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<td>Based on availability of data for use by investigators outside the parent protocol team(s) through the submission and approval of a data request for DACS and NWCS</td>
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<tr>
<td>Preparation of Statistical Analysis Plan for NWCS/DACS manuscripts</td>
<td>Timeline will vary</td>
<td>• Define Statistical Analysis Plan prior to initiation of data analysis. • Analyses using non-Statistical and Data Analysis Center (SDAC) statistical expertise must follow SOP ACTG-158, Requests for Data from ACTG Studies, for the procedure for conduct of secondary analyses when SDAC resources are not available.</td>
<td>Protocol/Non-protocol Statistician(s)</td>
</tr>
<tr>
<td>Completion of analysis report</td>
<td>Timeline will vary</td>
<td>• Send finalized analysis report to protocol chair(s)/lead investigator(s). • Notify ACTG Publications Office that analysis report has been sent.</td>
<td>Protocol/Non-protocol Statistician(s)</td>
</tr>
<tr>
<td>60-Day preparation of manuscript</td>
<td>Upon receipt of the finalized analysis report</td>
<td>• Oversee timely completion of manuscript and adherence to timelines. • Determine number and order of masthead authors; acknowledge ACTG support in the manuscript. (See Appendix 1: Writing Team Guidelines, Acknowledgements section.)</td>
<td>Committee Leadership/ Protocol/Non-protocol Investigators</td>
</tr>
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**Table Notes:**
- DACS: Data Analysis Center.
- ACTG: AIDS Clinical Trials Group.
- SDAC: Statistical Data Analysis Center.

**Responsibilities:***
- Protocol/Non-protocol Investigators
- Protocol/Non-protocol Statistician(s)
- Protocol/Non-protocol Investigators and/or Protocol/Non-protocol Statistician(s)
- Committee Leadership/Protocol/Non-protocol Investigators
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<th>EVENT</th>
<th>NWCS/DACS MANUSCRIPT TIMELINE</th>
<th>PROCEDURES</th>
<th>RESPONSIBLE PARTY(IES)</th>
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|       |                               | • Finalize manuscript within 60 days from date the analysis report was received by protocol/non-protocol investigator(s).  
• If there will be a delay in the submission of the manuscript for ACTG review, an extension request should be submitted (see Appendix 2: Requesting a Manuscript Writing Extension). | Protocol/Non-protocol Investigators  
Protocol/Non-protocol Investigators |
| 30-day team review of manuscript by masthead authors to include SDAC, the protocol chairs, and pharmaceutical/biomedical industry representatives of the parent protocols | Following 60-day writing period | • Send manuscript for 14-day review and sign-off (see Appendix 3: Distribution Lists for 14-day review distribution list). Pharmaceutical, biomedical industry, or external collaborators are allowed up to 30 days for review, unless otherwise specified in the parent protocols’ CTAs 1.  

**NOTE:** It is the Investigators responsibility to ensure that all of the pharmaceutical/industry reps have been allowed adequate time to review the manuscript. | Protocol/Non-protocol Investigators |
| Submission of manuscript for ACTG review following team review | 90 days after the analysis report is received by the investigators | • Submit manuscript to ACTG Publications Office, via Submission Central on the ACTG member website https://member.actgnetwork.org/pub/cs/review, after final team review.  
• If submitting to an Open Access journal, notify the ACTG Publications Office for determination of Open Access fee coverage (see Appendix 6: ACTG Publication Costs). | Protocol/Non-protocol Investigators |
| ACTG review of manuscript | Within 10 business days after manuscript is received from investigators | • Send manuscript to SC chair/vice chair/designated committee reviewer for approval/disapproval.  
• Send manuscript to additional review parties for review concurrent with committee review (See Appendix 3: Distribution Lists for ACTG Publications Office manuscript review distribution list). 1  
• Acquire list of masthead authors with significant financial interests, or a statement that none of them do, from the ACTG Financial Disclosure Coordinator (FDC). (See SOP ACTG-107, “ACTG Publications Office” 1) | ACTG Publications Office  
Financial Disclosure Coordinator |
<table>
<thead>
<tr>
<th>EVENT</th>
<th>NWCS/DACS MANUSCRIPT TIMELINE</th>
<th>PROCEDURES</th>
<th>RESPONSIBLE PARTY(IES)</th>
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</table>
| Completion of ACTG review | Within 10 business days after manuscript is received from the ACTG Publications Office | • Review manuscript and return manuscript endorsement sheet to ACTG Publications Office (see Appendix 4: Committee Reviewer Responsibilities).  
• Send endorsement response and additional review party comments to corresponding author.  
• Respond to review comments (via options below)  
  o Approved [and reviewer does not want to see MS again]: proceed with submission to journal.  
  o Approved and reviewer wants to see manuscript again prior to submission: incorporate comments and send revised manuscript and responses to ACTG Publications Office within 20 days.  
  o Disapproved: resubmit revised manuscript to ACTG Publications Office within 60 days for 10 day ACTG review as indicated above.  
  
**NOTE:** Substantial changes following ACTG review must be agreed on by the masthead authors and SC chair/vice chair/designated committee reviewer. If agreement cannot be reached, refer to the SASC chair for resolution. | SC Chair/Vice-Chair/designated reviewer  
ACTG Publications Office  
Protocol/Non-protocol Investigators |
| Revision and resubmission of manuscript 60 days after acceptance with revisions or rejection | Within 60 days of rejection following initial ACTG review | • Distribute revised manuscript, review comments, and responses to writing team, masthead authors, and protocol team to include SDAC, DAIDS, and the pharmaceutical representatives for a 2nd team review.  
  o Resubmit to the team review parties outlined in Appendix 3: Distribution Lists.  
• Resubmit revised manuscript to ACTG Publications Office, via | Protocol/Non-protocol Investigators |

Network-Specific Financial Disclosure and Conflict of Interest Procedures*.  
• Review manuscript and submit any comments to ACTG Publications Office.²
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<tr>
<th>EVENT</th>
<th>NWCS/DACS MANUSCRIPT TIMELINE</th>
<th>PROCEDURES</th>
<th>RESPONSIBLE PARTY(IES)</th>
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</thead>
</table>
| Submission to journal | Within 30 days after ACTG approval | Submission Central on the ACTG member website, for a second ACTG review prior to journal submission.  
- Failure to submit for a second ACTG Review within 60 days may result in sanctions, as described in Appendix 5: Sanctions.  
- Send manuscript for second 10-day ACTG review to SC Chair/Vice-Chair/designated reviewer.  
- Respond to second review comments via options listed in “Completion of ACTG Review” section above.  
- Ensure masthead authors’ disclosure of potential conflicts of interest as required by journal policy.  
- Prior to signing the journal publication agreement (or similar copyright transfer agreement)-  
  - Ensure the publishing agreement allows the paper to be posted to PubMed Central, in accordance with NIH Public Access Policy.  
  - Contact the ACTG Publications Office for assistance in retaining author rights for compliance to Public Access Policy.  
- If a journal requests a statement about access to data, use the following statement: “The authors confirm that all data are fully available upon request from sdac.data@sdac.harvard.edu with the written agreement of the AIDS Clinical Trials Group.”  
- If a journal requests a statement about access to data and statistical analysis programs, use the following statement: “Study data and statistical programming code are available upon request from sdac.data@sdac.harvard.edu with the written agreement of the AIDS Clinical Trials Group.”  
- At the time of journal submission, the journal must be notified that the manuscript was funded wholly or in part by NIH. | Investigators  
ACTG Publications Office  
Protocol/Non-protocol Investigators |
<table>
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<tr>
<th>EVENT</th>
<th>NWCS/DACS MANUSCRIPT TIMELINE</th>
<th>PROCEDURES</th>
<th>RESPONSIBLE PARTY(IES)</th>
</tr>
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</table>
| Journal acceptance for publication | Following notification of acceptance for publication | • If the manuscript is being published in a journal that does not deposit final published articles in PubMed Central, submit a request with the final peer reviewed version (e.g., Microsoft Word document), all tables, figures, and supplementary information, and a copy of the signed publication agreement (or similar copyright transfer agreement) to PubMed Central via NIHMS. Add the ACTG Network Grant number to the NIHMS at the time of submission. The ACTG Leadership and Operations Center at ACTGPublications@partners.org can be contacted with questions. The Leadership and Operations Center can submit the manuscript on behalf of the corresponding author as a last resort.  
• Approve the release and PubMed Central formatting of your manuscript when receiving the email notification from NIHMS.  
• If the authors are responsible for publication fees, see Appendix 6: ACTG Publication Costs. | Protocol/Non-protocol Investigators or senior author |
| Assignment of scientific contribution credit | Within 30 days after publication | • Obtain an electronic copy of the published manuscript and, if appropriate, assign scientific contribution credit for the annual site and laboratory performance evaluations in accordance with SOP ACTG-126, "ACTG Performance Measures and Standards". | Network Coordinating Center |
| Referencing ACTG published manuscripts | Following publication of manuscript online or in journal | • When submitting an application, proposal, or report to the NIH, the PubMed Central reference number (PMCID) must be included when citing ACTG papers that arise from NIH-funded research. | ACTG members |

1 Timelines codified in CTA may supersede timelines set in this SOP.

2 Please refer to [http://publicaccess.nih.gov/FAQ.htm](http://publicaccess.nih.gov/FAQ.htm) for an informative list of frequently asked questions.
5.2 **ACTG Abstracts**

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<th>EVENT</th>
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<th>PROCEDURES</th>
<th>RESPONSIBLE PARTY(IES)</th>
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</table>
| Team review of abstract | Prior to submission for ACTG review | • For main protocol or substudy abstracts, submit a request for team review to the writing team, masthead authors, and the protocol team, to include all current members including SDAC\(^3\), DAIDS\(^3\), the protocol chairs, and the pharmaceutical and biomedical industry representatives\(^2\) (if applicable).  
  o For substudies, the main study team and substudy team must be included.  
• For NWCS and DACS abstracts, submit a request for team review to the masthead authors to include SDAC if SDAC\(^3\) is a co-author, the protocol chair(s) of the parent protocol(s), and the pharmaceutical and biomedical industry representatives of the parent protocol(s). The ACTG Publications Office can be contacted for this information. | Writing Team Chair |
| Submission of abstract for ACTG review | Preferably at least 5 days and no fewer than 72 hours prior to conference organizer deadline\(^1\) | • Send analyses on which abstract is based to ACTG Network PI/chair and vice chair, SC chair and vice chair.  
• Submit abstract to ACTG Publications Office, via Submission Central on the ACTG member website, after final team review.  
• Send abstract to SC chair/vice chair/designated committee reviewer for approval/disapproval and to additional review parties\(^2\) for comments (see Appendix 3: Distribution Lists for ACTG Publications Office abstract review distribution list). | Protocol Statistician(s)  
  Writing Team Chair  
  ACTG Publications Office |
<table>
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<tr>
<th>EVENT</th>
<th>TIMELINE</th>
<th>PROCEDURES</th>
<th>RESPONSIBLE PARTY(IES)</th>
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<tbody>
<tr>
<td>ACTG review of abstract</td>
<td>72 hours prior to deadline</td>
<td>• Review abstract and complete abstract endorsement sheet sent by ACTG Publications Office (see Appendix 4: Committee Reviewer Responsibilities).&lt;br&gt;• Submit signed abstract endorsement sheet, which may include additional comments, to ACTG Publications Office upon completion of review.</td>
<td>SC Chair/Vice Chair/designated committee reviewer</td>
</tr>
<tr>
<td>Completion of ACTG review</td>
<td>At least 24 hours prior to conference submission deadline</td>
<td>• Communicate SC endorsement and all comments to corresponding and lead author.&lt;br&gt;• Respond to review comments (if approved, proceed with next step)&lt;br&gt;  o If not approved by the SC chair/vice chair/designated committee reviewer, either revise and resubmit for a second ACTG review a minimum of 24 hours prior to the conference submission deadline, withdraw the abstract from the conference (if already submitted), or send an appeal to the SASC/Executive Committee chairs.</td>
<td>ACTG Publications Office&lt;br&gt;Writing Team Chair</td>
</tr>
<tr>
<td>Submission to conference organizer</td>
<td>Within 5 days after ACTG approval</td>
<td>• Submit abstract to the ACTG Publications Office at the time of conference submission.</td>
<td>Writing Team Chair</td>
</tr>
<tr>
<td>Notification of abstract disposition</td>
<td>Within 10 days after notification by conference organizer</td>
<td>• Provide a copy of the disposition to ACTG Publications Office. <em>Failure to notify the ACTG Publications Office that an abstract has been accepted may result in actions by the SC leadership.</em></td>
<td>Writing Team Chair</td>
</tr>
<tr>
<td>If abstract is accepted and dissemination of summaries is required by the TSG/SC</td>
<td>At least 48 hours prior to release to the general public</td>
<td>See Section 4.4 table for CTU/CRS Scientific Summaries.</td>
<td>ACTG Network Coordinating Center</td>
</tr>
<tr>
<td>If abstract is accepted and development of press releases is found to be required</td>
<td>Prior to conference</td>
<td>See Section 4.5 table for Press Releases.</td>
<td>Pharmaceutical, biomedical industry representatives, protocol team, or NIAID/DAIDS</td>
</tr>
<tr>
<td>EVENT</td>
<td>TIMELINE</td>
<td>PROCEDURES</td>
<td>RESPONSIBLE PARTY(IES)</td>
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</tr>
<tr>
<td>If abstract is not accepted: Revision and resubmission of abstract</td>
<td>Preferably at least 5 days and no fewer than 72 hours prior to the conference organizer deadline</td>
<td>• Notify the ACTG Publications Office of abstract rejection prior to resubmission to another conference. If major revisions occur, re-review is required, otherwise the endorsement stands. Submit revised abstracts to the ACTG Publications Office, via Submission Central on the ACTG member website, for a second ACTG review prior to submission to another conference. Team review is required prior to resubmission for ACTG review.</td>
<td>Writing Team Chair</td>
</tr>
<tr>
<td>Preparation of conference presentation</td>
<td>Prior to conference</td>
<td>• Acknowledge the ACTG and include the ACTG logo on presentation materials. The ACTG logo can be found on the ACTG member website, under Shared Resources, General ACTG information, About ACTG folder (<a href="https://member.actgnetwork.org/cms/folder/6169">https://member.actgnetwork.org/cms/folder/6169</a>). • Circulate final/near-final poster and/or slides to protocol team, including pharmaceutical, biomedical industry, or other external collaborators, for review. Posters and/or slides do not need to be submitted to the ACTG Publications Office for ACTG review.</td>
<td>Writing Team Chair</td>
</tr>
<tr>
<td>Dissemination of accepted abstracts</td>
<td>At least 1 day prior to conference start date</td>
<td>• Send copies of accepted abstracts to all CTU PIs and CRS Leaders.</td>
<td>ACTG Publications Office</td>
</tr>
<tr>
<td>Presentation of conference paper</td>
<td>Within 2 weeks following the conference</td>
<td>• Send an electronic copy of the finalized presentation to ACTG Publications Office to be posted on the ACTG website.</td>
<td>Writing Team Chair</td>
</tr>
</tbody>
</table>

1 If data not available in timeframe, alternative review process may be determined by SC, SASC, and Executive Committee chairs.
2 Timelines codified in CTA may supersede timelines set in this SOP. If the company changes its name, merges with or is acquired by another company, a representative of the new company must receive the manuscript. Timelines and requirements for manuscript review may be superseded by Clinical Trials Agreement stipulations.
3 SDAC statistician responsible for distributing for SDAC review; SDAC responsibility to ensure distribution of analysis reports to ACTG Network PI/Chair and Vice Chair and SC Chair and Vice Chair for both abstracts and manuscripts. DAIDS protocol member (Clinical Representative) responsible for distributing for internal DAIDS review.
### 5.3 ACTG CTU/CRS Summaries

<table>
<thead>
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<th>EVENT</th>
<th>TIMELINE</th>
<th>PROCEDURES</th>
<th>RESPONSIBLE PARTY(IES)</th>
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</table>
| Preparation and review of CTU/CRS Scientific Summary and Participant Summary | Summaries are required per the SC leadership. | - Prepare Scientific Summary and Participant Summary.  
- Review and approve the Scientific and Participant Summaries prior to dissemination. | Protocol Team  
Relevant SC leadership, ACTG Network PI/Chair, SASC chair, DAIDS, pharmaceutical, biomedical industry, or other external collaborators |
| Dissemination of CTU/CRS Scientific and Participant Summaries | At least 48 hours prior to the first public presentation of the results | - Distribute Scientific Summary with Participant Summary to the CTU PI, CRS Leader, and CTU and CRS Coordinators with a statement indicating that the information is embargoed until public presentation or publication. | CTS |

### 5.4 ACTG Press Releases

5.4.1 If prepared for published or presented abstracts reporting preliminary study results prior to completion of final study results, only data from published/presented abstract is normally permitted for use in press release. Additional data may be included with the express permission of the protocol team and the ACTG Network PI/Chair.

5.4.2 Press releases to be issued by the ACTG on behalf of its own studies should be prepared by the protocol team.

5.4.3 The Protocol team, pharmaceutical, biomedical industry, or external collaborators, and NIAID/DAIDS must work directly with the ACTG Communications Manager, actg.communications@fstrf.org, on all press releases.
<table>
<thead>
<tr>
<th>EVENT</th>
<th>TIMELINE</th>
<th>PROCEDURES</th>
<th>RESPONSIBLE PARTY/PARTIES</th>
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</thead>
<tbody>
<tr>
<td>Preparation of a press release by pharmaceutical, biomedical industry, or external collaborators</td>
<td>When the study is complete and an abstract is published/presented, but final results and/or primary manuscript are not published or if primary/secondary manuscript is scheduled for publication.</td>
<td>• Protocol team members who are aware of press releases in development by pharmaceutical, biomedical industry, or external collaborators should notify the ACTG Communications Manager.</td>
<td>Protocol Team</td>
</tr>
<tr>
<td>Request permission to publish a press release</td>
<td>When the study is complete and an abstract is published/presented, but final results and/or primary manuscript are not published or if primary/secondary manuscript is scheduled for publication.</td>
<td>• Submit the press release, with a request to publish it, to ACTG Publications Office for approval by Protocol Team, SC chair, ACTG Network PI/Chair, the ACTG Communications Manager and NIAID/DAIDS.</td>
<td>Pharmaceutical, biomedical industry, or external collaborators, Protocol Team, or NIAID/DAIDS</td>
</tr>
<tr>
<td>Publication of press release</td>
<td>Following approval by protocol team, SC chair, ACTG Network PI/Chair and NIAID/DAIDS</td>
<td>Submit a copy of the published press release to the ACTG Publications Office.</td>
<td>Pharmaceutical, biomedical industry, or external collaborators, Protocol Team, or NIAID/DAIDS</td>
</tr>
</tbody>
</table>

¹Timelines codified in CTA may supersede timelines set in this SOP.

Questions and comments regarding press releases should be directed to the ACTG Communications Manager, actg.communications@fstrf.org
6.0 REFERENCES
6.1 SOP ACTG-109, NWCS Development and Review
6.2 SOP ACTG-106, DACS Development and Review
6.3 SOP ACTG-126, Site Performance Measures and Standards
6.4 SOP ACTG-107, ACTG Network-Specific Financial Disclosure and Conflict of Interest Procedures
6.5 SOP ACTG-101, Study Closure, Data Cleanup and Study Analysis Preparation
6.6 SOP ACTG-158, Data Request (DR) Development and Review
6.7 SOP ACTG-120, Appeal and Grievance
6.9 ACTG CTU and CRS Grant numbers at https://member.actgnetwork.org/cms/folder/6211

7.0 INQUIRIES
Questions and comments regarding these procedures may be directed to the ACTG Publications Office at ACTGPublications@partners.org.

8.0 SOP APPROVAL

<table>
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<tr>
<th>APPROVING BODY</th>
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<tr>
<td>ACTG Executive Committee</td>
<td>05/13/2019</td>
</tr>
<tr>
<td>NIAID Division of AIDS</td>
<td>05/14/2019</td>
</tr>
</tbody>
</table>

9.0 REVISION HISTORY

<table>
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<th>REPLACES</th>
<th>DATE OF REVISION</th>
<th>RATIONALE FOR REVISION/RETIREMENT</th>
</tr>
</thead>
</table>
| 13.0      | 08/07/2019     | 12.0     | 04/30/2019      | • For Scope added “governed by subcontract agreements executed by University of California, Los Angeles (UCLA) on behalf of the ACTG.”
|           |                |          |                 | • Removed “Core” from protocol team.
|           |                |          |                 | • Clarifications were made to fix discrepancies between SOP 111 and 101. The timelines should match between the two SOPs.
|           |                |          |                 | • Added Clinicaltrials.gov results submission and definition changes to align with CT.gov regulations and the SDAC internal SOP.
|           |                |          |                 | • Removed Executive Summaries.
|           |                |          |                 | • Added a statement that all presentations of studies (oral, written, poster, and other) must include sex and gender breakdowns. If the information is not available, presenters can simply indicate as much. |
Appendix 1: Writing Team Guidelines

Writing Team Membership

The Protocol Team is responsible for forming the writing team, which usually comprises the following parties—

1. Protocol Chair or Co-Chairs
2. Protocol Vice Chair(s)
3. Protocol Statistician(s)
4. Protocol Team investigators
5. Immunologist, virologist, and/or pharmacologist, as appropriate

Guidelines for Masthead Authorship and the Author Order

The masthead should include those who have made significant contributions to the design, conduct, or analysis of the study. Masthead authorship should not be based solely on participation as a protocol team member, data manager, CTS, laboratory staff, field representative, pharmaceutical or biomedical industry collaborators, or other external collaborators, or on the number of study participants accrued to the study. The inclusion of authors, and their roles and authorship order should be determined as the manuscript is in preparation, and finalized by the time the manuscript is ready for submission. In the event of disagreements regarding masthead authorship, the SC leadership should be consulted. If agreement cannot be reached, an appeal should be submitted to the SASC. Any subsequent appeals should follow the ACTG appeals procedure (SOP ACTG-120, “Appeal and Grievance”).

For studies that enrolled participants from fewer than six institutions, one investigator from each institution, contributing study participants may be considered for masthead authorship, if journal limitations on numbers of authors will allow.

For studies involving more than six institutions, institutions with high participant enrollment may have one investigator considered for masthead authorship. The address of each co-author should reflect his/her site. If the protocol chair or vice chair is from a high enrolling institution and is already an author, he/she can place another investigator from that institution on the masthead. In cases where the large numbers of enrollees render the inclusion of a single representative from each site with high accrual infeasible, the protocol team may consider developing an alternative plan for allowing masthead authorship by investigators from participating sites. This plan should be presented to the SASC for consideration prior to the circulation of a draft manuscript for ACTG review.

Journal Criteria for Authors. The number of authors on the masthead of an article may be limited by journal guidelines. Masthead authorship must meet the criteria for the journal.

Masthead Author Relocation. In instances where study work is completed or substantially conducted at one institution and the author relocates to another institution prior to the manuscript being submitted to a journal, both the author’s current and former institutions should be cited. It is the responsibility of the relocated author and the site leader of the former CRS to ensure that both institutions are cited in the publication.

Acknowledgment of ACTG, NIAID, and other Support for Annual Reporting and Scientific Contribution Credit

Appropriate acknowledgment of ACTG support is required for annual reporting to sponsor institutes and for ACTG-related manuscripts to receive relevant scientific contribution credit in the annual site and laboratory performance evaluations, in accordance with SOP ACTG 126,
"ACTG Performance Measures and Standards".

1. In compliance with the NIH Grants Policy Statement, include the following citation in all papers published under the auspices of the ACTG:

"Research reported in this publication was supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health under Award Number UM1 AI068634, UM1 AI068636 and UM1 AI106701. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health”. Support of collaborating Institutes or Centers, should be included with this statement, notably the National Institute of Dental and Craniofacial Research (NIDCR) and the National Cancer Institute for OHARA and malignancy studies; National Institute on Drug Abuse (NIDA), National Institute of Mental Health (NIMH) and National Heart, Lung and Blood Institute (NHLBI) for the studies they have supported.

2. Cite the ACTG’s sponsor institute and all other NIH institutes that contributed funds to the ACTG’s efforts.

Acknowledgement of Participating Sites

Acknowledgement of the participating sites is required as follows:

- Study-related primary and major secondary manuscripts must include an acknowledgements appendix. Please contact the ACTG Publications Office to obtain names and grant numbers from each participating site. The list of CTU and CRS Grant numbers is available on the ACTG member website under the Publications Resources page, https://member.actgnetwork.org/cms/folder/6211.
  - For studies with CRSs/CTUs that have received support from additional center grants include the following citation:
    "Supported in part by a grant(s) funded by the National Center for Advancing Translational Sciences (or subsequently designated NIH center)"

- For NWCS, DACS and minor secondary manuscripts, a statement acknowledging the participating clinical research sites of the parent studies is sufficient.

Acknowledgement of ACTG Repository

If the ACTG Repository provided the study specimen(s), cite the ACTG Repository and include a link to the ACTG Repository Website, www.specimenrepository.org.

Documentation of National Clinical Trial (NCT) Number

ACTG clinical trials are registered with the ClinicalTrials.gov web-based protocol registration system. A unique identifier (NCT number) is provided that should be documented in the final manuscript, according to the journal. The ACTG Publications Office or CTS can be contacted for this number.
Appendix 2: Requesting a Manuscript Writing Extension

If the Writing Team Chair is not able to submit a final manuscript draft to the ACTG Publications Office within 90 days of the protocol chair receiving the finalized primary or secondary analysis report, an additional 30-day extension may be granted by the SC Chair.

The Writing Team Chair must submit a written request for an extension to the ACTG Publications Office at least 2 weeks prior to the deadline and include an explanation for the delay. The ACTG Publications Office will forward the request to the SC chair and SC Coordinator. The SC Coordinator will subsequently provide written notification of the SC’s approval or disapproval of the writing extension to the Writing Team Chair and copy the ACTG Publications Office.

If the draft manuscript is not received within 90 days of receipt of the analysis, the SC leadership may impose sanctions (See Appendix 5: Sanctions). The SC Leadership must communicate any sanctions to the ACTG Publications Office.
Appendix 3: Distribution Lists

Manuscript 14-day team review and sign-off distribution list (prior to ACTG review submission)—

For Primary/Secondary Manuscripts:

- Writing Team
- Masthead authors
- Protocol team, to include all current members including SDAC**, DAIDS***, the protocol chairs, and the pharmaceutical and biomedical industry representatives* (if applicable)
  - For substudies, the main study team & substudy team must be included

For NWCS and DACS Manuscripts:

- Masthead authors to include SDAC if SDAC** is a co-author
- Protocol Chair(s) of the parent protocol(s)
- Pharmaceutical and biomedical industry representatives of the parent protocol(s)

*If the company changes its name, merges with or is acquired by another company, a representative of the new company must receive the manuscript. Timelines and requirements for manuscript review may be superseded by Clinical Trials Agreement (CTA) stipulations.

**The protocol statistician is responsible for distributing the manuscript for SDAC review; SDAC is also responsible for distribution of the analysis reports to the ACTG Network PI/Chair and Vice Chair and SC Chair and Vice Chair for both abstracts and manuscripts.

***The DAIDS Clinical Representative on the protocol is responsible for distributing the manuscript for internal DAIDS review.

The ACTG Publications Office can assist with providing the contact information for the appropriate review parties.

ACTG Publications Office manuscript review distribution list—

- SC Chair/Vice Chair/designated committee reviewer*
- ACTG Network PI/Chair
- SASC Chair
- ACTG Network Laboratory PI
- SDAC
- DAIDS
- CTU PIs or CRS Leaders of participating (for primary manuscripts only)

* If a secondary manuscript falls under a different committee than the primary manuscript, a SC chair/vice chair/designated committee reviewer from both committees must review the manuscript.
ACTG Publications Office abstract review distribution list—

- SC chair/Vice Chair/designated committee reviewer
- ACTG Network PI/Chair
- SASC Chair
- ACTG Network Laboratory PI
- DAIDS
- SDAC
- Pharmaceutical Representatives
  - For NWCS and DACS abstracts, pharmaceutical representative(s) of the contributing protocol(s)
- Protocol Chair(s) (if not on the masthead)
  - For NWCS and DACS abstracts, protocol chair(s) of contributing protocol(s)
Appendix 4: Committee Reviewer Responsibilities

The decision to approve or disapprove submission of a manuscript to a journal, or an abstract to a conference, is solely that of the SC chair/vice chair, or the designated committee reviewer if the chair and vice chair are conflicted.

The SC Chair/Vice Chair/designated committee reviewer is responsible for the following—

1. Ensuring the scientific integrity of the abstract or manuscript.

2. Ensuring that the Writing Team adheres to the ACTG publication policies on authorship; ACTG acknowledgment; citation of the protocol number(s); and citation of the NCT number.

3. Ensuring the authors have circulated the manuscript or abstract to the pharmaceutical and biomedical industry representatives involved with the study during team review; the right to review manuscripts is an important part of the CTA between the pharmaceutical and biomedical companies and the NIAID/DAIDS, acting on behalf of the ACTG.

4. Ensuring that potential conflicts of interest are appropriately acknowledged.

5. Requiring SDAC review, if necessary

6. Confirming that primary and major secondary manuscripts are (a) credited to the ACTG Network LOC, LC, and SDAC grants (b) primarily funded by the Network and (c) contain an acknowledgement appendix containing names and grant numbers for each site. In the event that publication costs (see Appendix 6: ACTG Publication Costs) are accrued, these criteria must be met in order for the ACTG Central Group to cover publication costs.

7. Confirming that NWCS and DACS and minor secondary manuscripts are (a) credited to the LOC, LC, and SDAC Network grants and (b) contain a statement acknowledging the participating clinical research sites.

8. Agreeing on substantial changes made to the abstract or manuscript following ACTG review.
Appendix 5: Sanctions

Manuscripts

Potential actions and/or sanctions include but are not limited to, appointment of a new Writing Team Chair, deduction of scientific credit points from the relevant CRS or Specialty Laboratory during annual site and laboratory evaluations, respectively; prohibition of the Writing Team Chair from chairing future studies and/or removal of the Writing Team Chair from the protocol or scientific team. In the event that another Writing Team Chair is appointed, but is unable to complete the manuscript publication process, the responsible SC Chair will have the option to appoint a third Writing Team Chair. This decision will be made in conjunction with the SASC. If a new Writing Team Chair is appointed, the SC Coordinator is responsible for communicating the SC’s new manuscript timeline to the new Writing Team Chair and the ACTG Publications Office.

In the event that an author prefers to submit to a journal that consistently does not comply with the NIH timeline for submitting articles to PMC, the SC Chair and/or Network Leadership have the option to restrict the Writing Team from submitting the manuscript to the referenced journal.
Appendix 6: ACTG Publication Costs

The ACTG Central Group will cover the following publication costs for primary and secondary manuscripts if the SC Chair confirms that they have been (a) primarily funded by the Network, (b) credited to the ACTG Network LOC, LC and SDAC grants, and (c) deposited and signed off by the lead author in the PMC system. *

- Review fees
- Page charges

Any additional author fees charged for approved manuscripts, including costs for publishing in an Open Access journal and charges for color figures, will be reviewed by the Executive Committee and SASC Chairs on a case-by-case basis.

The ACTG will not cover Open Access costs for publishing in journals that do not require Open Access. If submitting a request for the ACTG to cover Open Access costs in a journal that requires Open Access, justification for submitting to an Open Access journal must be provided. If the publication cost is for a color figure(s), provide justification for publishing in color.

The ACTG Central Group will not cover publication costs for NWCS/DACS manuscripts.

Once confirmation is received indicating that the ACTG Central Group will cover the publication costs, the ACTG Publications Office will provide the author with information for the invoice.

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