

Policy Name: Data Ownership	Policy Number: 10.1
Section: Publications – 10.0	Date Revised: February 8, 2019

10 Publications Committee charter and mission guidelines

“The Publications Committee shall review existing policies and best practices concerning authorship of scientific publications, and shall recommend to the Executive Committee for its approval a set of requirements for authorship of Alliance publications. These requirements shall be in the form of a guidance policy for Alliance publications and shall address rules governing authorship and disclosure of conflict of interest for Alliance publications. The chair and vice chair of the Publications Committee shall include one individual who is a scientific leader and one who is a community oncology leader. The Publication Committee shall include representatives from the Central Protocol Operations Program and the Statistics and Data Management Program, as well as other members as deemed appropriate. The Publications Committee shall meet at a frequency of not less than once yearly. The Publications Committee shall also adjudicate in a timely manner any issues related to publication of Alliance manuscripts, and make recommendations concerning these matters to be acted upon by the Executive Committee.”

— Statement from the Alliance Constitutions and Bylaws

10.1 Data ownership

Data generated by Alliance Group activity, using Alliance resources, or associated with the Alliance belong to the Alliance. Therefore, the Alliance, through its publication policy, has oversight over the use and publication of any and all Group data. All planned abstracts or manuscripts reporting results of Alliance studies to a meeting or journal for publication are to undergo pre-submission review and approval, based on this Policy and Procedures document.

Publications resulting from data-sharing agreements require only administrative review to check for basic elements (e.g., Alliance group name, grants) and do not require full Alliance review.

Policy Name: Committee Members	Policy Number: 10.2
Section: Publications – 10.0	Date Revised: January 1, 2018

10.2 Committee members

Members of the Alliance Publications Committee are nominated by the committee chair/co-chairs to serve 3-year terms (renewable one time), and are expected to attend a minimum of 75 per cent of committee meetings.

Policy Name: Group Review Members	Policy Number: 10.3
Section: Publications – 10.0	Date Revised: January 1, 2018

10.3 Group Review members

Reviewer's Group Role	Comments
All co-authors of publication	
Chair/Co-Chairs Publications Committee*	
Chief Financial Officer	
Committee Chair	<i>Applicable studies only</i>
Director, Biospecimens and Correlative Science Operations*	<i>Translational studies only</i>
Director, Central Operations*	
Director, Regulatory Affairs	
Executive Officer	<i>Applicable studies only</i>
Group Administrator	
Group Chair*	
Group Statistician*	
Manager, Publications Operations	
NCI CTEP or DCP representative	
Industry representative, according to study agreement	<i>Applicable studies only†</i>
Executive Committee members	<i>Half of the EC membership (excluding those asterisked in this table) is selected to review publications in 2 5-month rotations; the entire EC reviews publications in December and January to provide sufficient coverage for ASCO abstracts.</i>

*Member of the Executive Committee who reviews publications in all rotations.

†Determined by Director of Regulatory Affairs

Policy Name: Abstract and Manuscript Preparation	Policy Number: 10.4
Section: Publications – 10.0	Date Revised: June 1, 2021

10.4 Abstract and manuscript preparation

10.4.1 General principles

The Alliance guidelines build on the publicly available *International Journal of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journals* (<http://www.icmje.org>).

The study chair is responsible for providing leadership and writing manuscripts/abstracts for publications that describe an Alliance study. The document entitled “CHECKLIST – Recommended Content for Alliance Manuscripts and Meeting Abstracts” provides guidance related to title page, authorship, acknowledgements, scientific content for different sections, as well as template wording for support, monitoring, informed consent, locations of data collection and statistical analyses, randomization scheme, quality assurance, meta- or pooled analysis, and data lock. All authors are expected to review and follow this checklist.

The study chair sends the initial draft manuscript/abstract to all the co-authors for review, including the faculty and staff statisticians. All authors, including those assigned authorship based on accrual, are responsible for careful and meaningful review. The first author takes into account all comments and suggestions by co-authors and incorporates them into the revised draft, as appropriate. After initial co-author review, the study chair sends the revised draft to the publications coordinator (publications@AllianceNCTN.org) as an MS Word file; this way the Alliance files are properly up to date. This revised draft is sent for Group Review (see sections 10.5.3 and 10.5.4).

The author is responsible for submitting the final Alliance-approved version of the manuscript to a journal, and for advising the publications team (publications@alliancencn.org) when this has been done (see section 10.6. Abstract or Manuscript Submission to Meeting or Journal). It is the responsibility of the corresponding author to collect and send to the journal all journal-specific conflict of interest forms prior to manuscript submission for publication. Any individual with a conflict of interest that is sufficient to make them ineligible for a study chair role cannot serve as either first or senior (last) author of an Alliance publication.

10.4.2 Cover page

It is important for the study number(s) to appear early in the manuscript/ abstract for ease of retrieval in literature searches. The title section of the cover page of the manuscript should indicate the Alliance or legacy study number(s) about which the manuscript is written. As example: “Phase III Alliance A1K study of drug A vs. drug B for treatment of X”. For abstracts and manuscripts generated from the ACOSOG, CALGB, and NCCTG legacy groups, the recommendation is to add

Policy Name: Abstract and Manuscript Preparation	Policy Number: 10.4
Section: Publications – 10.0	Date Revised: June 1, 2021

“Alliance” after the study number. As example: “Phase III ACOSOG A1K (Alliance) study of drug A vs. drug B for treatment of X”.

If it is not possible to include all study numbers in the title, the author should insert wording such as “A combined analysis of Alliance studies” in the title; include the study numbers within the abstract or introduction section.

The cover page of a manuscript also contains a paragraph indicating the supporting grant numbers for all authors listed; the National Institutes of Health (NIH) grant number for an author should reflect the main member institution with which the author was affiliated when the study was activated. Appropriate acknowledgment of other funding sources should be included as well (e.g., the Breast Cancer Research Foundation or company XYZ).

NIH requires that publication or oral presentation of NCI-supported work acknowledge that support. Publications and presentations as described here include abstracts, press releases, print-media articles/manuscripts, electronic media articles/presentations, and letters related to findings and results from NCI-sponsored studies. The Alliance publications team and the Alliance communications specialist insert grant support information into Alliance-related publications/presentations before Group Review. **Therefore, the corresponding author is responsible for ensuring that these grants appear in the final published version.**

The Alliance requires that industry support be acknowledged on all publications.

10.4.3 Authorship

Alliance authorship guidelines follow those of the publicly available [International Committee of Medical Journal Editors \(ICMJE\)](#) recommendations for authorship:

“The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; **AND**
- Drafting the work or revising it critically for important intellectual content; **AND**
- Final approval of the version to be published; **AND**
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Policy Name: Abstract and Manuscript Preparation	Policy Number: 10.4
Section: Publications – 10.0	Date Revised: June 1, 2021

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged.”

If there are questions or discrepancies related to author order based on the study chair’s decision and the publications guidelines, as seen below, arbitration is required by the Alliance Publications Committee chair/co-chairs and the Alliance Group chair, with input from the other Group Review members.

10.4.3.1 Publication on the primary study endpoint

The listing and order of authorship for a manuscript/abstract for a primary study endpoint is determined by overall workload contribution, intellectual contribution, and participant accrual. Each author is responsible for obtaining any required clearances from his/her own institution (or network).

The first author of the manuscript/abstract is usually the study chair or co-chair. A study chair who moves to a non-Alliance institution may continue to serve in the full capacity of study chair with the agreement of the appropriate committee chair and if no conflicts of interest have arisen because of the move of the study chair. The original study chair therefore retains authorship rights by virtue of serving in the full capacity of the study chair role.

The first author is generally followed by the study’s primary statistician. Authorship should be granted to the responsible executive officer. An exception occurs when two or more investigators contributed equally to the study. In this case, the statistician should be next author and an asterisk and footnote must explain the previous positions: “These authors contributed equally to the study.” When the publications team receives an abstract or manuscript in which the statistician is not the second author, the publications coordinator contacts the statistician to confirm that the authorship order is appropriate.

The study community co-chair should be included as an author if appropriate by ICMJE recommendations stated above. If the modality co-chair participated in the design of the study and wrote the modality section of the protocol, they should be an author on primary endpoint publications. Pathologists, radiologists and other specialists who perform quality assurance (QA) for a study should be included in the authorship of any publications that result from the study, unless the publication is independent of QA results of their findings. The decision for inclusion of an Alliance quality assurance specialist/data manager, clinical research professional or nurse as a co-author is to be made by the study chair in consultation with the

Policy Name: Authorship	Policy Number: 10.4
Section: Publications – 10.0	Date Revised: June 1, 2021

primary statistician and disease/modality committee chair, and must be made according to ICMJE recommendations.

Other individuals making significant contributions according to ICMJE recommendations may be listed.

Institutional authorship based on accrual is separate from (and in addition to) study chair, committee chair or other contributors. Institutional authorship representation on primary study publications is awarded to an institutional network whose participant accrual contribution fulfills the following guidelines:

Total number of participants in the study	Number of participants at a network, based on total study accrual
Fewer than 100 total study accrual	25% of the total or 8 participants, whichever is less
100 – 199 total study accrual	8% of the total or 12 participants, whichever is less
200 – 299 total study accrual	7% of the total or 17 participants, whichever is less
300 – 399 total study accrual	6% of the total or 21 participants, whichever is less
400 – 499 total study accrual	5% of the total or 22 participants, whichever is less
500 or greater total study accrual	Authorship is awarded to the three networks that accrue the most participants, not based by percentage or number of participants enrolled

The principal investigator of a network makes the assignment of authorship after being informed by the publications operations manager or publications coordinator of network merit. The network principal investigator is best suited to determine the assignment of authorship and may assign himself/herself, another physician in the same or another specialty, or an individual from the main member or an affiliate. In most cases, authorship is assigned to the highest accruing investigator in the institutional network. Institutional nurses or clinical research professionals making significant contributions should also be considered for authorship. Generally, the

Policy Name: Authorship	Policy Number: 10.4
Section: Publications – 10.0	Date Revised: June 1, 2021

individual given the authorship assignment should be someone who was working at the institution during the period of accrual and who made substantive contributions to accrual at the institution. All authors should be included in manuscript preparation and approval.

For manuscripts/abstracts involving other National Clinical Trial Network (NCTN) group studies, it is not necessary to include all other NCTN group institutions, but it is expected that groups that enrolled >10% of patients should have at least one author included in the report of treatment studies.

All primary manuscripts (excluding those for multi-group studies) also acknowledge each network that enrolled participants on the study. The relevant local principal investigator, their network, and grant numbers are listed in that appendix.

When the study is a limited access pilot of fewer than 30 patients, involving only a few institutions, the study chair, primary statistician and committee chairs should discuss authorship. Ideally, all institutions participating will be represented.

10.4.3.2 Publication on a secondary (correlative) study

A secondary (correlative) study may include observations utilizing existing datasets or compilation of results from several studies. The secondary study may have been approved as a sub-study in an original protocol document, or may be a new study that was proposed by an Alliance or non-Alliance investigator. The work may involve biospecimens, quality of life, symptom analyses, and economic analyses, among others. The intention of the Alliance authorship policy is to be appropriately inclusive, consistent with authorship guidelines from major journals and the ICMJE.

Information related to the Alliance and its grant numbers should be in the cover page of secondary manuscripts.

1. Authorship on publications of a secondary study included in the original Alliance or legacy protocol

All of the following are invited to participate in review of abstract/manuscript data, publication development and approval and should receive authorship if appropriate by ICMJE recommendations:

- Study chair, study co-chair, executive officer, and community co-chair of the original study. Authorship by a modality co-

Policy Name: Authorship	Policy Number: 10.4
Section: Publications – 10.0	Date Revised: June 1, 2021

chair on secondary endpoint publications should be a function of their involvement in the secondary analysis.

- Study chairs or champions from other NCTN groups that accrued patients or samples to the secondary study
- Correlative study statistician and primary statistician of the original study if different
- Pathologists, radiologists and other specialists who perform quality assurance (QA) for the study, unless the publication is independent of QA results of their findings.
- Accrual authors

For accrual authors on CALGB and NCCTG publications, the principal investigator of the highest accruing network selects the network author based on investigator accrual or other study contribution. No minimum accrual threshold is required for the network or selected author.

2. Authorship on publications of a secondary study not in an original Alliance or legacy protocol; study proposed by Alliance investigator

New secondary studies include observations utilizing existing datasets or specimens, or a compilation of results thereof from several studies that were not part of the original objectives of the primary study or studies.

a. Intellectual authorship: When manuscripts/abstracts are prepared for new secondary studies, potential authorship should be extended to the following individuals. *However, authorship determination should be based on ICMJE recommendations (see section 10.4.3, first paragraph)*

- Researchers performing the secondary study,
- Study chair(s) of original Alliance study or studies,
- Statistician of the new secondary study,
- Primary statistician of original Alliance study or studies.
- Co-chairs from other cooperative groups that accrued any patients or specimens may be included if Alliance author or Alliance committee chair requests.
- Pathologists, radiologists and other specialists who perform quality assurance (QA) for a study, unless the publication is independent of QA results of their findings.

Policy Name: Authorship	Policy Number: 10.4
Section: Publications – 10.0	Date Revised: June 1, 2021

After primary study chair(s), primary statistician(s), QA specialists and researchers, other investigators who were involved in the primary study or studies may not necessarily be included in secondary study publications; instead, authorship is determined by an individual’s contribution specific to the secondary study and by ICMJE recommendations. Order of authorship should reflect the magnitude and effort contributed by each author to the secondary analyses, which may be independent of the primary studies’ analyses or accrual.

- b. Authorship based on accruals and new data: Authorship based solely on accrual is not a criterion for this category of abstract or manuscript. Accrual investigators are recognized in an acknowledgement section rather than with authorship, unless they are among the investigators conducting the secondary use study, in which case authorship depends upon contribution.

It is expected that all investigators who contributed new data to the secondary analyses will also

- be involved in interpretation of those data
- be given the opportunity to participate fully in preparation of resultant manuscripts/ abstracts
- be co-authors on those manuscripts/ abstracts.

This may also apply to non-tissue secondary abstracts/ manuscripts if the data collected by the investigators from the collaborative groups will be utilized.

- c. Authorship in Alliance-led meta-analyses: When abstracts or manuscripts are based on Alliance-led analyses using data shared from multiple studies, authorship will include all members of the research teams involved in the current research. Alliance also encourages inclusion of the original study teams in publication authorship, with the understanding that ICMJE recommendations are followed. These policies apply to Alliance-led meta-analyses of data sets obtained from the Alliance, as well as to Alliance-led meta-analyses of Alliance data sets available through the NCTN Data Archive or Project Data Sphere

Policy Name: Authorship	Policy Number: 10.4
Section: Publications – 10.0	Date Revised: June 1, 2021

3. **Authorship on publications of a secondary study not in an original Alliance or legacy protocol; study proposed by non-Alliance investigator**

This category includes abstracts and manuscripts led by outside investigators who have been granted access to Alliance data or biospecimens.

Authorship decisions regarding the non-Alliance study chair, statistician and researchers performing the secondary study are made by the non-Alliance investigator and team.

NCI rules do not mandate that the Alliance investigators be considered for authorship. We suggest that outside investigators consider including the following Alliance leadership team in the preparation and formal approval of the manuscript:

- Alliance study chair(s), of original Alliance study or studies.
- Alliance primary statistician(s) of original Alliance study or studies
- Investigators who contributed annotated tumor specimens

For publications resulting from data sharing of multiple studies, including Alliance studies, Alliance encourages the inclusion of the original study teams in publication authorship, with the understanding that ICMJE recommendations are followed.

Policy Name: Abstract and Manuscript Timelines	Policy Number: 10.5
Section: Publications – 10.0	Date Revised: February 8, 2019

10.5 Abstract and manuscript timelines

10.5.1 Timelines for abstract and manuscript preparation

The process of abstract and manuscript generation for phase III studies begins promptly after the Alliance Data and Safety Monitoring Board (DSMB) has determined that the study results may be released and the study chair has completed case evaluations. In accordance with NCTN policy, the Alliance expects preliminary results of major phase III trials to be presented at a scientific meeting within 8 months of completion of the study analysis (if not sooner based on the relevance of the results). It is an NCTN requirement that a full manuscript on the primary study results be submitted for publication in the peer-reviewed literature (not as an abstract) within 1 year of the availability of the primary study results based on the completion date of the study recorded in the U.S. National Library of Medicine database, clinicaltrials.gov.

The Alliance Publications Committee monitors compliance with NCTN policy and communicates with authors, committee chairs, the Group chair, the Alliance Board of Directors, and the Alliance Executive Committee about delays. Action may be taken as indicated in the Delinquency in Manuscript Preparation section below.

For pilot studies, phase I-II studies, and nontreatment studies, the process begins when the study chair has received the study summary from the study's primary statistician. Of note, the statistician may need to conduct additional analyses in collaboration with the study team. Once the statistical analyses are completed, the statistician sends a copy of the analyses to the study chair and notifies the disease/modality chair (refer to the Statistical Summary Report Timelines Document).

The first abstract/manuscript is expected to be based on the mature primary endpoint of the study. Submission of abstracts before data on the primary endpoint are completed is not generally endorsed, but may be considered on individual cases. Some examples are description of unexpected toxicities, enrollment procedures or data, and companion studies that are not dependent on the primary endpoint. This decision to submit an abstract before primary endpoint data are mature is made as a collaborative effort between the study chair, study primary statistician, committee chair, Group chair, and Publications Committee.

Almost all abstracts submitted to a meeting must be followed by a full manuscript (except in special situations that should be discussed with the Alliance Publications coordinator prior to the abstract submission); the manuscript should be sent to the Alliance publications coordinator (publications@AllianceNCTN.org) for Group Review no later than 6 months after the meeting. We suggest that the abstract author

Policy Name: Abstract and Manuscript Timelines	Policy Number: 10.5
Section: Publications – 10.0	Date Revised: February 8, 2019

create a draft manuscript by the time of meeting presentation using the statistical analysis that is prepared for the meeting abstract to optimize time and effort. This initial draft can be used as a guide from which to develop a final version that is sent to potential co-authors, etc., prior to submission to the Alliance publications coordinator.

For publications in which an abstract is not prepared prior to developing a draft manuscript, the draft manuscript should be sent to the publications coordinator within 2 months after completion of the statistical summary report.

10.5.2 Delinquency in manuscript preparation

A manuscript on the primary endpoint results of a phase III study must be submitted for publication in the peer-reviewed literature within 1 year of the availability of the primary study results. As stated above, it is expected that a draft manuscript is completed at the time of data presentation at a medical meeting. When a study chair has not completed a draft manuscript according to this timeline, the disease or modality committee chair initiates a discussion with the study chair, as a warning (cc to publications@AllianceNCTN.org). After receiving a warning notice from the committee chair, the study chair has 30 days to submit a first draft of the manuscript to the protocol office.

If the study chair is unable to complete the manuscript in the expected time period, 2 actions by the disease and modality committee chairs may follow: (1) reassignment of first authorship and (2) prevention of the delinquent author from chairing a future Alliance concept or study for at least one year. The appropriate disease and modality committee chairs then request from the Group chair (and Publications Committee chair/co-chairs) permission to reassign the manuscript to an investigator responsible for a large percentage of accrual or with a substantial intellectual contribution to the study. The reassignment of authorship of a paper rests with the appropriate disease or modality chairs, who should in turn notify both the new author and the study's executive officer of the reassignment. The disease or modality chair should clarify to the new author that the first draft of the manuscript should be ready within 30 days after re-assignment.

10.5.3 Timelines for review and revision of abstracts submitted to the Alliance publications coordinator

A meeting abstract must be submitted by the first or corresponding author to the publications coordinator (publications@AllianceNCTN.org) as a Word document at least 2 weeks prior to the meeting abstract submission deadline. The author receives scientific comments from Group reviewers typically within 3 days after the publications coordinator sends the abstract for review. Comments concerning authorship may also be sent to the corresponding author. After revising the abstract

Policy Name: Abstract and Manuscript Timelines	Policy Number: 10.5
Section: Publications – 10.0	Date Revised: February 8, 2019

based on Group Review, the first author must send the revised abstract to co-authors for their approval. When the abstract is accepted, the author must send the acceptance email and the final submitted abstract to all co-authors and to the publications coordinator within 1 week after acceptance.

10.5.4 Timelines for review and revision of manuscripts submitted to the Alliance publications coordinator

The publications coordinator (publications@AllianceNCTN.org) reviews authorship within 2 working days and submits the authorship to the study chair within those 2 working days. Barring any procedural delays or discrepancies/concerns between the study chair and publications coordinator’s author list and order, the publications coordinator submits the manuscript for Group Review within 5 working days. The Alliance manuscript review (aka Group Review) members are described in the Group Review section above.

Reviewers are expected to provide written input to the publications coordinator within 7 working days. All abstracts and manuscripts (except those resulting from data sharing) must be reviewed by an independent Alliance faculty statistician.

All comments from the Group Review should be sent to the manuscript’s first author, the corresponding author, the chair of the Publications Committee, and the publications operations manager. The first author is expected to discuss suggestions with the study statistician, review comments, and complete a second version of the manuscript within 4 weeks. Inability to meet this timeline should be discussed with the modality/disease committee chair. Based on the situation, further discussion with the Publications Committee chair may be required, to better assist the author.

10.5.5 Approval of abstracts and manuscripts

All comments received from reviewers during Group Review are sent to the chair/co-chair of the Alliance Publications Committee. The Publications Committee chair/co-chair are responsible for approving abstracts and manuscripts, or requesting revisions followed by re-review.

Policy Name: Abstract or Manuscript Submission	Policy Number: 10.6
Section: Publications – 10.0	Date Revised: February 8, 2019

10.6 Abstract or manuscript submission to meeting or journal

The study chair revises the manuscript/abstract based on internal and external reviews outlined above and sends the co-authors the revised publication for their approval. The study chair or corresponding author submits the approved manuscript/abstract to the journal or association for review, complying with all submission requirements. See section 10.10 for required author actions that pertain to the NIH Public Access Policy at time of manuscript submission.

The study chair also sends a copy of the submitted manuscript/abstract to the publications coordinator (publications@alliancencn.org) for inclusion in the Alliance publication database within 1 week after submission.

Policy Name: Publication of Abstract or Manuscript	Policy Number: 10.7
Section: Publications – 10.0	Date Revised: February 8, 2019

10.7 Publication of abstract or manuscript

The study chair/corresponding author advises the publications coordinator (publications@AllianceNCTN.org) of the status of all abstracts and manuscripts submitted to a meeting or journal for publication. Letters of acceptance and a PDF file of the published abstract or printed manuscript must be sent by the study chair/corresponding author to the publications coordinator within 14 days of availability. This is necessary for the Alliance publication database to be accurate and complete (including the full citation). This material is reviewed every on an ongoing basis by the Publications Committee. To facilitate access to Group study results, Alliance publication citations are posted in the publications section on the Alliance Web site.

Policy Name: Press Release	Policy Number: 10.8
Section: Publications – 10.0	Date Revised: January 1, 2018

10.8 Publicizing Research Information

All communication related to the dissemination of Alliance research to external audiences is handled by the Alliance communications specialist. This includes all written or recorded communication (i.e., press releases, news releases, press statements, video releases) directed to members of the news media, stakeholders, and the public, regarding the activation, progress, results and findings of Alliance research. This also relates to all communication generated by an institution or industry partner based on Alliance research. Such communication must be submitted the communication specialist (communications@AllianceNCTN.org) for review at least one week prior to its release. Also refer to Section 14.3, Dissemination of Information to the General Public.

Policy Name: Summary of Study Results for the Public	Policy Number: 10.9
Section: Publications – 10.0	Date Revised: January 1, 2018

10.9 Summary of study results for the public

The lead author must submit the completed plain language study results summary template to the publications coordinator (publications@AllianceNCTN.org) when the manuscript is sent for Alliance Group review. If a manuscript is not accompanied by a completed template, Group review will be delayed until its receipt.

For a phase III or randomized phase II study, a public study result summary of the trial design, goals and results is created by the Publications Committee, with input from the lead author of the manuscript, Patient Advocate Committee and Oncology Nursing Committee, using the plain language template for consistent and understandable information. The primary audience for public study result summaries includes study participants.

The Alliance web content administrator posts the public summary to the Alliance website at a time that coincides with publication of the manuscript.

Policy Name: Public Access	Policy Number: 10.10
Section: Publications – 10.0	Date Revised: February 8, 2019

10.10 NIH Public Access Policy

The NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008). The law states:

“SEC. 218. The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine’s PubMed Central an electronic version of their final peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.”

The NIH Manuscript Submission (**NIHMS**) system facilitates the submission of peer-reviewed manuscripts to PubMed Central (**PMC**) in support of the NIH Public Access Policy.

Under Alliance policy, the author is responsible for ensuring that the manuscript appears in PMC no later than 12 months after official publication. The official date of publication is listed in the PubMed citation display for a paper immediately after the journal title abbreviation. An "epub ahead of print" date for a citation in PubMed is not considered the official date of publication, and these papers are still considered in press.

10.10.1 Overview of manuscript submission to PubMed Central

There are four methods defined by the NIH to ensure the deposit of a manuscript into PMC in compliance with the NIH Public Access Policy: Methods **A**, **B**, **C**, and **D** (Tables 1 and 2). A journal or publisher uses one of these four, or a combination. Some methods require more author involvement than do others. If a journal uses Method A, the manuscript is deposited into PMC without author involvement. If a journal uses Method C, the author must take all steps to ensure deposit into PMC. Methods B and D involve both the author and the journal/publisher. In all methods, the author must also take steps to link the manuscript to Alliance grant(s).

At the time of manuscript submission, the author must determine the method used by the publisher or the journal and follow the steps required for that method. The instructions provided in this policy section are designed to help the author identify journal submission method and understand author actions that lead to compliance.

Policy Name: Public Access	Policy Number: 10.10
Section: Publications – 10.0	Date Revised: February 8, 2019

Table 1. Overview of methods of compliance with NIH Public Access Policy

Question	Version of Manuscript Deposited and Associated Methods and Approvals	
	Final Published Article	Final Accepted Peer-Reviewed Manuscript
What is the difference between a final published article and a final accepted peer-reviewed manuscript?	This is the journal’s authoritative copy of the paper, including all modifications from the publishing peer review process, copyediting and stylistic edits, and formatting changes.	This is the author's final manuscript version of a peer-reviewed paper accepted for journal publication, including all modifications from the journal’s peer review process.
What is the submission process for the two different versions of the manuscript?	Publisher posts the final published article directly to PMC to be made publicly available no later than 12 months after the official date of publication. <i>Therefore, the author is not required to deposit the final peer-reviewed manuscript into NIHMS at acceptance.</i>	Final peer-reviewed manuscript is required to be submitted via the NIHMS <i>upon acceptance if the publisher does not intend to post the final published article to PMC.</i> Depending upon the method, the publisher or author deposits files. The NIHMS converts the files to the PMC native format.
What are the NIH-defined methods of submission used by journals to deposit a version of the article?	<ul style="list-style-type: none"> • Method A: These journals automatically post an NIH-supported published paper directly to PMC if the author advises of NIH support. • Method B: Author must make special arrangements for these journals and publishers to post the published paper directly to PMC, since they do not automatically do so. <i>If an author does not make arrangements, then he/she must use Method C.</i> 	<ul style="list-style-type: none"> • Method C: Journal does not submit manuscript. <i>Author must submit final peer-reviewed manuscript to the NIHMS.</i> • Method D: These publishers will submit final peer-reviewed manuscripts to the NIHMS if the author advises of NIH support. <p>Author is responsible for ensuring manuscript is submitted to the NIHMS upon acceptance for publication.</p>
Who approves the submission? (Initial approval)	Publisher	Author, via NIHMS. NIHMS sends notifications to author.
Who approves the PMC web version? (Final approval)	Publisher	Author, via NIHMS. NIHMS sends notifications to author.
Who is responsible for ensuring compliance?	Author	Author

Policy Name: Public Access	Policy Number: 10.10
Section: Publications – 10.0	Date Revised: February 8, 2019

Table 2. Compliance method used by journals that frequently publish Alliance manuscripts (as of 2/8/2019)

<u>Method A journals</u> <u>(Level of PMC participation)</u>	<u>Method B journals with fee</u> (See column 4. Most also offer Method D for no fee)	<u>Method C journal</u>	<u>Method D journals</u> (See column 2. Most also offer Method B for a fee)
<i>Ann Oncol</i> (NIH portfolio) <i>Blood</i> (NIH portfolio) <i>Blood Advances</i> (Full) <i>BMC Cancer</i> (Full) <i>Br Med J (BMJ)</i> (Full) <i>Cancer Medicine</i> (Full) <i>Eur J Cardiothorac Surg</i> (NIH portfolio) <i>Haematologica</i> (Full) <i>Health Edu Res</i> (NIH portfolio) <i>J Clin Oncol</i> (NIH portfolio) (submitted at 12 mo) <i>JCO Precision Oncol</i> (NIH portfolio) <i>JNCI</i> (NIH portfolio) <i>Neuro-Oncology</i> (Full) (submitted at print issue) <i>Neuro-Oncology Practice</i> (NIH portfolio) (submitted at print issue) <i>PLOS One</i> (Full) <i>The Oncologist</i> (Full)	<i>Am J Clin Oncol</i> <i>Ann Surg</i> <i>Ann Surg Oncol</i> <i>Ann Thoracic Surg</i> <i>Biol Blood Marrow Transplant</i> <i>Breast Cancer Res Treat</i> <i>Br J Haematol</i> <i>Cancer</i> (has section in subm app) <i>Cancer Epidemiol, Biomarkers & Prevention</i> <i>Cancer Nursing</i> (at publication) <i>Clin. Pharmacol. Ther.</i> <i>Clinical Trials</i> (no D) <i>Int J Cancer</i> <i>Int J Radiat Biol Phys</i> <i>JAMA</i> (no fee, at publication--print) <i>JAMA Oncol</i> (no fee, at publication--print) <i>J Am Coll Surg</i> <i>J Am Geriatr Soc</i> <i>J Neuro-Oncol</i> <i>J Thorac Cardiovasc Surg</i> <i>J Thorac Oncol</i> <i>Leuk Lymph</i> <i>Pediatric Blood Cancer</i> <i>Pharmacogenet. Genomics</i> <i>Qual Life Res</i> <i>Support Cancer Care</i> <i>Translational Research</i>	<i>Am J Roentgenol</i> <i>JNCCN</i>	<i>Am J Clin Oncol</i> <i>Ann Surg</i> <i>Ann Surg Oncol</i> <i>Ann Thoracic Surg</i> <i>Biol Blood Marrow Transplant</i> <i>Breast Cancer Res Treat</i> <i>Br J Haematol</i> <i>Cancer</i> <i>Cancer Epidemiol, Biomarkers & Prevention</i> <i>Cancer Res</i> <i>Clin Cancer Res</i> (au must request) <i>Clin Colorectal Cancer</i> <i>Clin. Pharmacol. Ther.</i> <i>Int J Cancer</i> <i>Int J Radiat Biol Phys</i> <i>J Am Coll Surg</i> <i>J Am Geriatr Soc</i> <i>J Geriatric Oncology</i> <i>J Neuro-Oncol</i> <i>J Thorac Cardiovasc Surg</i> <i>J Thorac Oncol</i> <i>Lancet</i> <i>Lancet Haematology</i> <i>Lancet Oncology</i> <i>Leukemia</i> (opt-in) <i>Leuk Lymph</i> <i>NEJM</i> <i>Pediatric Blood Cancer</i> <i>Pharmacogenet. Genomics</i> <i>Qual Life Res</i> <i>Support Cancer Care</i> <i>Translational Research</i>

Policy Name: Public Access	Policy Number: 10.10
Section: Publications – 10.0	Date Revised: February 8, 2019

10.10.2 Author responsibilities based on journal methods

10.10.2.1 Method A journals

[These journals](#) make the [final published version](#) of all NIH-funded articles available in PubMed Central (PMC) no later than 12 months after publication without author involvement. This may be at an NIH agreement level that requires the author to alert the publisher to NIH funding. The author should inform the publisher of NIH funding, since that information may be required. The author is not required to submit the final peer-reviewed manuscript into NIHMS upon acceptance.

Author action:

At the time of manuscript submission, the author must advise the journal publisher that the manuscript is supported by NIH funding and that it therefore falls under the NIH public access policy. Once advised, the publisher will assist the author with public access policy compliance by depositing the final published version of the manuscript into PMC.

10.10.2.2 Method B journals

[These journals and publishers](#) have a selective deposit agreement with NIH to post individual *final published articles* in PubMed Central (PMC) on a case-by-case basis. They do not automatically post every NIH-funded paper in PMC. The submitting author must arrange with the journal at the time of submission to post the specific article; this usually involves selecting the journal's fee-based open access option for publishing that article. The Alliance does not reimburse the author for the fee.

Many Method B journals also offer the alternative Method D, which is a free deposit of the final accepted peer-reviewed manuscript into NIHMS (Method D; see below). (See Table 2 for journals that use Method B.)

If a Method B journal does not offer Method D and the author does not make any arrangement with the journal or publisher (with or without a fee) at time of submission, *the author must deposit the manuscript through the NIHMS (see required author actions for Method C journals).*

Author action: **At the time of manuscript submission**, the author must advise the journal publisher that the manuscript is supported by NIH funding and arrange for the journal to either (1) post the final published article in PMC (for a fee) or (2) post the final accepted peer-reviewed manuscript into NIHMS (for no fee, Method D). The author must take this action for the publisher to handle steps for public access policy compliance. *Otherwise, the*

Policy Name: Public Access	Policy Number: 10.10
Section: Publications – 10.0	Date Revised: February 8, 2019

author must submit the manuscript through the NIHMS (see required author actions for Method C journals).

10.10.2.3 Method C journals

Method C journals and publishers do not assist the submitting author with public access compliance. The author must deposit the final peer-reviewed manuscript into NIHMS upon acceptance by a journal. The author should complete action steps below as soon as the journal accepts the manuscript in order to allow sufficient time for completion of all steps involved in moving it toward PMC. If the manuscript is not in PMC within 90 days after the official publication date, the NIH considers the manuscript noncompliant.

Author actions: All steps are necessary for compliance

1. At the time of acceptance the author should

Submit the final peer-reviewed accepted manuscript to NIHMS. Method C submissions can be started from within My Bibliography.

2. After submitting the manuscript to NIHMS, the author should

- a. Advise the Alliance publications coordinator (by sending email to publications@AllianceNCTN.org) of the NIHMSID assigned to the manuscript.
- b. Approve the initial submission for processing in the NIHMS system when notified by NIHMS.
- c. Link the paper to all Alliance grant(s) that directly supported it (indicated in the support section of the Alliance-approved version of the manuscript).
- d. Review and approve the PMC-ready web version for inclusion in PMC after the submitted files have been converted, when notified by NIHMS.

Note: The assigned author will receive an email notifying him/her when action is required in NIHMS. NIHMSIDs expire after 90 days

10.10.2.4 Method D journals

These journal publishers have volunteered to deposit the *final accepted peer-reviewed manuscript* into NIHMS when the author advises them that it falls under the NIH Public Access Policy. The publisher has no agreement with PMC. Authors are responsible for ensuring that the manuscript is deposited (by the publisher or, if necessary, by themselves) into the NIHMS upon acceptance for publication.

If the manuscript is not in PMC within 90 days after the official publication date, the NIH considers the manuscript noncompliant.

Author actions:

Policy Name: Public Access	Policy Number: 10.10
Section: Publications – 10.0	Date Revised: February 8, 2019

1. **At the time of manuscript submission**, the author must advise the journal publisher that the manuscript is supported by NIH funding and arrange for the journal to post the final accepted peer-reviewed manuscript into NIHMS. This step is necessary for the publisher to assist the author with public access policy compliance.
2. **At the time of acceptance**, the author should confirm with the publisher that the manuscript will be submitted to NIHMS.
3. **After the manuscript is submitted to NIHMS the author should**
 - a. Approve the initial submission for processing in the NIHMS system, when notified by NIHMS.
 - c. Link the paper to all Alliance grant(s) that directly supported it (indicated in the support section of the Alliance-approved version of the manuscript).
 - d. Review and approve the PMC-ready web version for inclusion in PubMed Central after the submitted files have been converted, when notified by NIHMS.

Note: The assigned author will receive an email notifying him/her when action is required in NIHMS. NIHMSIDs expire after 90 days.

10.10.3 Resources for NIH Public Access Policy

For questions concerning Alliance compliance with NCI Public Access Policy, contact publications@alliancenctn.org. A description of the process can be found at the Alliance website, in the [study chair training portion](#).

Authors may also contact the NIHMS or PubMed Central help desks using the following URLs or e-mail addresses:

NIH Public Access: <https://publicaccess.nih.gov/contact> NIHMS:

https://nihms.nih.gov/db/sub.cgi?page=email&from=grant_suggest&mid=

PubMed Central: nihms-help@ncbi.nlm.nih.gov

Training on an author's responsibilities in complying with the NIH Public Access Policy can be found at <http://publicaccess.nih.gov/communications.htm> and at <http://www.nihms.nih.gov/help/#slideshow>.

Answers to frequently asked questions are available at [NIHMS FAQ](#).

Policy Name: Quick View of Alliance Publications Timelines	Policy Number: 10.11
Section: Publications – 10.0	Date Revised: February 8, 2019

10.10.4 Alliance Monitoring of Compliance with NIH Public Access Policy

The Alliance publications team reminds authors about policy and submission methods; monitors compliance and alerts authors of delays; and communicates with the committee chair and the Publications Committee about the possibility or presence of non-compliance.

The publications team requests to be informed of the journal of interest when an author sends a manuscript for Alliance Group review. When the team sends an e-mail to the author communicating Alliance approval of a manuscript, that e-mail contains information about the NIH Public Access Policy and submission methods that apply to the journal of interest. Authors are asked to advise the publications team if they intend to submit to a different journal so that the team can send new instructions.

Authors are required to advise the Alliance publications team (publications@AllianceNCTN.org) within one week after manuscript submission and within two weeks after manuscript acceptance; at both time points, the team reminds the author to follow the steps outlined in section 10.10.2. The team may assist authors with completion of required steps and with contacting publishers, journals, NIHMS and eRA Commons. On an ongoing basis, the publications team checks the status of assignment of NIHMSIDs and PMCIDs.

The publications team communicates with the author, committee chair, and Publications Committee about noncompliance. The Publications Committee chair or co-chairs correspond with other committee chairs and the Group chair, when necessary, to suggest action (see section Delinquency in Manuscript Preparation).

Policy Name: Quick View of Alliance Publications Timelines	Policy Number: 10.11
Section: Publications – 10.0	Date Revised: February 8, 2019

10.11 Quick view of Alliance publication timelines

Type of publication	Timelines		
	<u>Initial Author Deadline</u>	Group Review Period	<u>Subsequent Author Deadlines</u>
Meeting abstract	<i>Send to publications coordinator:</i> 2 weeks prior to meeting submission deadline or per online schedule	3 days for scientific review 7 days for operations review during high volume periods	<i>Send to publications coordinator:</i> 1. Copy of submitted abstract within 1 week after submission 2. Acceptance email and PDF of published abstract no later than 2 weeks after available
Manuscript with no prior meeting abstract	<i>Send to publications coordinator:</i> 2 months after completion of the statistical summary report along with completed public study summary template, if applicable	7 days for scientific review	<i>Send to publications coordinator:</i> 1. Next draft within 4 weeks 2. Notification of submission and submitted manuscript within 1 week after submission 3. Acceptance letter and PDF of published manuscript no later than 2 weeks after available
Manuscript that follows a meeting abstract	<i>Send to publications coordinator:</i> 6 months after presentation at meeting along with completed public study summary template, if applicable	7 days for scientific review	<i>Send to publications coordinator:</i> 1. Next draft within 4 weeks 2. Notification of submission and submitted manuscript within 1 week after submission 3. Acceptance letter and PDF of published manuscript no later than 2 weeks after available
Alliance-approved manuscript submitted to journal	Journal submission: Determine the journal's NIH Public Access Policy method to assure compliance with government policy if manuscript is accepted	NA	NA
Accepted manuscript	Manuscript acceptance: If journal uses NIH Public Access Method C or if author has not made submission agreement in Method B, submit manuscript to NIHMS and follow instructions in section 10.10	NA	If journal submission Method C or D was used, or if author has not made submission agreement in Method B, provide the following in NIHMS, per sect. 10.10: Approval of submitted or posted materials (initial NIHMS approval) Approval of PMC web version (final NIHMS approval)
External study communications, if applicable	<i>Send to publications coordinator and communications specialist:</i> 1 week prior to press release	1 week	NA
Contact information			
Alliance publications coordinator: publications@AllianceNCTN.org			
Alliance communications specialist: communications@AllianceNCTN.org			
PubMed Central: http://www.ncbi.nlm.nih.gov/sites/ehelp?Ncbi_App=entrez&Db=pubmed			
NIHMS: https://nihms.nih.gov/db/sub.cgi?page=email&from=grant_suggest&mid=			