19 PUBLICATIONS REQUIREMENTS AND PROCEDURES

19.1 Overview, Key Principles, and Definitions

Publications in peer-reviewed journals and presentations at scientific conferences represent the most significant products of the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network's research. The results of IMPAACT studies are to be published and shared in a timely manner in accordance with the National Institutes of Health (NIH) Public Access Policy. This section describes the process and requirements for preparation and review of abstracts, manuscripts, executive summaries, and other documents through which study-related results are disseminated. These procedures are intended to ensure timely development and dissemination of high quality products reporting the results of IMPAACT studies or otherwise using IMPAACT-related data.

All abstracts and manuscripts using IMPAACT data must undergo an IMPAACT Network review before being submitted to a conference or journal. The results of the main study (primary manuscript) must be submitted – and ideally published – prior to those of sub-studies and secondary manuscripts, unless otherwise approved by the IMPAACT Management Oversight Group (MOG).

These procedures should be reflected in the terms of Clinical Trials Agreements (CTA), Memoranda of Understanding (MOU), or alternative agreements approved by the IMPAACT MOG for studies with co-sponsoring agencies, companies, or other clinical trials networks, and studies in which data are collected and analyzed by a network or group other than the IMPAACT Statistical and Data Management Center (SDMC).

All IMPAACT publications must meet the criteria for authorship, disclosure, scientific integrity, and other requirements of peer-reviewed scientific journals.

Protocol Chair Responsibilities

The protocol chair assumes overall responsibility for ensuring publication of the study findings in a timely manner. The results of each study should be reported in at least one peer-reviewed publication addressing the primary objective(s) within a reasonable time frame as outlined below. The protocol chair may designate a writing team to draft manuscripts or abstracts; the writing team chair is then responsible for completion and submission for IMPAACT review within the timeline specified below, with continued oversight by the protocol chair. The protocol chair will ensure that analysis and publication of secondary or sub-study results do not interfere with the analysis or publication of the primary study results and will work closely with the publications coordinator at the Operations Center to track the manuscript development progress and to address any concerns that may arise.

For studies likely to generate multiple manuscripts, the protocol chair may elect to designate a subset of the protocol team to function as a study-specific publications committee to assist in performing the responsibilities described for the protocol chair. This committee will review and prioritize manuscript/abstract proposals from team members and others and would minimally include the protocol chair and statistician(s), with other protocol team members included as needed. The SDMC will contribute to the planning and prioritization of various manuscripts for a study, ensuring that analyses for each can be completed as scheduled. Prioritization is critical as all planned primary and secondary analyses cannot be expected to proceed at once. The list of secondary analyses will need to be carefully reviewed and prioritized, and in some cases, the analyses may have to be completed by someone outside of SDMC.

Table 19-1. Definitions

Primary manuscript	Manuscript that reports findings related to the primary study objective(s) and outcome measures as described in the study protocol. Findings associated with secondary objectives may also be included. A protocol may have more than one primary publication. For example, a protocol may have more than one primary publication when a study is conducted in multiple stages and has a primary objective for each stage. For each IMPAACT study, the primary manuscript must be submitted for publication prior to secondary and sub-study manuscripts unless otherwise approved by the IMPAACT MOG.
Secondary manuscript	Manuscript that reports findings related to secondary study objectives and outcome measures as described in the study protocol, or scientific questions outside the primary objectives, e.g., baseline data reports, secondary objectives specified in the protocol, cross-protocol data, or analysis of specimens collected as part of a study but used for analyses not previously specified in the study protocol.
Abstract	Brief report of IMPAACT study data prepared for submission to a conference; may be classified as a regular abstract or a late-breaker abstract

Table 19-1. Definitions

New Works Concept Sheet (NWCS)	A proposed investigation involving use of existing biological specimens from an IMPAACT (or PACTG) study (or studies) that may or may not require IMPAACT funding and may or may not involve analysis work by SDAC. Unless the IMPAACT Network has designated the study as concluded or openly available for use by investigators outside of the protocol team, the objectives of the proposed investigation should not overlap with the objectives stated in the study protocol or with secondary analyses defined by the protocol team after receipt of the final analysis report. The objectives should not overlap with those specified in an approved IMPAACT NWCS that is not yet completed.
Data Analysis Concept Sheet (DACS)	A proposed investigation involving analysis of existing data from an IMPAACT (or PACTG) study (or studies) to be undertaken by SDAC with IMPAACT funding. Unless the IMPAACT Network has designated the study as concluded or openly available for use by investigators outside of the protocol team, the objectives of the proposed investigation should not overlap with the objectives stated in the study protocol or with secondary analyses defined by the protocol team after receipt of the final analysis report. The objectives should also not overlap with those specified in an approved IMPAACT DACS or NWCS that is not yet completed.
Data requests (DR)	A proposed investigation for which existing data from an IMPAACT (or PACTG) study are being requested for analyses to be performed without IMPAACT funding. (Note that a Statistical and Data Analysis Center [SDAC] statistician may be among the proposing investigators, but would not be seeking IMPAACT support for the work.) Unless the IMPAACT Network has designated the IMPAACT study as concluded or openly available for use by investigators outside of the protocol team, the objectives of the proposed investigation should not overlap with the objectives stated in the study protocol or with secondary analyses defined by the protocol team after receipt of the final analysis report. The objectives should also not overlap with those specified in an approved IMPAACT DACS or NWCS that is not yet completed. The statistical design of the research project and associated data analyses must be undertaken by the proposing investigators without IMPAACT funding.
Primary Completion Date	The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome measure (may or may not be the same as the closed to follow-up date, depending on the study design)
Closed to Follow-up Date	The date that the final participant completed the last study follow-up visit
IMPAACT Publications Group	Group responsible for reviewing IMPAACT manuscripts and abstracts on the behalf of the network prior to journal/conference submission. The Publications Group includes the IMPAACT network chair and vice chair, the SDMC principal investigator (PI) or designee, the Laboratory Center (LC) PI, representatives of National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Child Health and Human Development (NICHD), and National Institute of Mental Health (NIMH), and the relevant scientific committee (SC) chair
Protocol team	The team members whose names appear in the protocol roster, which usually includes pharmaceutical/industry representatives and other study sponsors/collaborators

Table 19-1. Definitions

Writing team	A subgroup of the protocol team who collaborate to write an abstract or manuscript. Under certain circumstances, specialists who are not protocol team members may be included.
Masthead authors	Individuals listed as authors on a manuscript or abstract
Publications coordinator	Operations Center staff member who facilitates and tracks development, submission, review, and outcome of manuscripts and abstracts that use IMPAACT data, through the following address: impaact.pubscoord@fstrf.org
Executive Summary	Summary of the results of Phase III or certain other IMPAACT studies that could alter the standard of care for HIV-related treatment or prevention or the design or conduct of ongoing or future clinical trials; prepared by the protocol chair, statistician, medical officer (MO), clinical trials specialist (CTS), and other team members based on the final analysis report for dissemination to site investigators/staff and industry or other collaborators prior to or at the same time as public presentation or publication of the results, as needed
Site Investigator Letter	Limited scientific summary of the main trial results; disseminated to participating sites prior to public presentation or publication of the results, if a full Executive Summary is not warranted, or when changes to an ongoing study are necessitated by emergent findings from that study, another investigation, or other external factors such as a relevant change in treatment guidelines
Participant Letter	A letter for study participants (or parents/legal guardians) summarizing or describing the study results and their implications or changes to an ongoing study necessitated by emergent findings from that study, another investigation, and/or other external factors such as a relevant change in treatment guidelines
Lay Summary	A brief document summarizing information (study results, etc.) presented in a manuscript – written in language appropriate for the communities in which the research is conducted and prepared by the manuscript authors. Lay summaries are required for manuscripts reporting study findings that have clinical implications, as determined by the writing team chair, are reviewed by the IMPAACT Community Advisory Board (ICAB), and are to be disseminated prior to or at the same time as publication of the results.
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
PubMed Central (PMC)	The NIH digital archive of full-text, peer-reviewed journal articles; its content is publicly accessible and integrated with other databases (http://www.ncbi.nlm.nih.gov/pmc/)
Publication costs	Author fees associated with publishing peer-reviewed manuscripts

19.2 Development and Review of Manuscripts

19.2.1 Primary Manuscripts

The timeline and process for development and review of the primary manuscripts are outlined in Table 19-1 and described starting in Section 19.2.1. Manuscripts reporting the primary results of IMPAACT studies are generally expected to be developed and submitted for internal IMPAACT review within 9 months (36 weeks) after the primary completion date or closed to follow-up date (whichever comes first) as follows:

- Data entry complete: 4 weeks from primary completion or closed to follow-up date
- Data cleaned and ready for analysis (considered the "study data complete" date): 8 weeks after data entry is complete
- Data analyzed and results provided to protocol chair and writing team: 8-12 weeks after data are cleaned and ready for analysis
- Draft manuscript submitted for IMPAACT review: 12 weeks after the final analysis report is received by the writing team (with the general expectation that the manuscript will be fully prepared within 8 weeks after the protocol chair's receipt of the final analysis report, leaving 4 weeks for all masthead authors, protocol team members, corporate sponsors/collaborators to sign off, unless otherwise specified in the CTA or other third party agreement). Text describing the background, study design, and other trial aspects can be drafted while data analysis is underway; i.e., need not await availability of results.

As further described in Section 7, results for all primary outcome measures must be entered into ClinicalTrials.gov within one year of the primary completion date. Results for secondary outcome measures with completion dates prior to or concurrent with the primary completion date must also be entered within one year after the primary completion date. These entries are required regardless of whether the results have been published.

19.2.2 Secondary Manuscripts

The timeline and process for development and review of secondary manuscripts are outlined in Table 19-2 and described starting in Section 19.2.2. Following receipt of the primary final analysis report by the protocol chair, the protocol team (or designated subset) begins developing the list of proposed secondary analyses, potential manuscripts and writing teams. Within eight weeks after receipt of the primary final analysis report, the protocol chair submits this list to the publications coordinator for tracking purposes.

The list should include the following for each secondary manuscript:

- Proposed writing team chair and brief title and description of each manuscript,
- List and status of laboratory samples and assay results required for the manuscript, and
- Expected timeline for analysis completion, considering the steps outlined above for primary manuscripts. As all secondary data analyses cannot proceed at the same time, preparation of secondary manuscripts typically requires prioritization.

The writing team chair for each secondary manuscript will work with the Statistical and Data Analysis Center (SDAC) to determine the statistical analysis plan – with some relevant analyses expected to have been completed as part of the primary analysis and the rest to be completed within a specified time frame. The timeline for secondary data analysis and manuscript development relative to the primary manuscript may vary depending on overall prioritization, completion of necessary laboratory assays, and other factors

affecting data availability and/or analyses; however, the general expectation is similar to that for primary manuscripts; once the analysis report is submitted to the writing team chair, the draft manuscript is expected to be submitted to the publications coordinator for IMPAACT review within 12 weeks, inclusive of eight weeks for manuscript development and four weeks for review by masthead authors, protocol team members, and corporate sponsors/collaborators (unless otherwise specified in the CTA or other third party agreement, as described for primary manuscripts).

The results of the main study/project primary manuscript must be submitted for publication prior to those of secondary (or sub-study) manuscripts, unless otherwise approved by the IMPAACT MOG (e.g., based on the recommendation of a Data and Safety Monitoring Board [DSMB]). The protocol chair will ensure that analysis and publication of secondary or sub-study results do not interfere with the analysis or publication of the primary study results and will work closely with the publications coordinator at the Operations Center to track the manuscript development progress and to address any concerns that may arise.

The IMPAACT review process for secondary manuscripts is the same as for primary manuscripts.

As further described in Section 7, results for any secondary outcome measures with completion dates after the primary completion date must be entered into ClinicalTrials.gov within one year after the respective completion dates for the secondary outcome measures. These entries are required regardless of whether the results have been published.

19.2.3 Manuscripts from DACS and NWCS

Procedures for submission and review of DACS and NWCS are detailed in Section 15. The timeline and process for development and review of the manuscripts from DACS and NWCS are outlined in Table 19-4. The timeline for preparation of the relevant analysis report may vary depending on a number of factors including availability of data and assay completion. However, once the analysis report is available, the expectations and procedures for manuscript development and review are the same as for primary and secondary manuscripts.

19.2.4 Manuscripts from DR

Procedures for submission and review of DR are detailed in Section 15. Any publications associated with a DR should include acknowledgement of provision of data by IMPAACT; however, the timeline and process for development and review of the manuscripts from a DR need not follow the procedures outlined in Table 19-4 or described in Sections 19.2.5-19.2.7. Any abstracts or manuscripts resulting from a DR should be sent to the IMPAACT publications coordinator prior to journal submission for review by the IMPAACT Publications Group and to confirm the appropriate acknowledgements.

Table 19-2. Timeline for Development and Review of Primary Manuscripts, including Timetable for Writing Team Formation and Manuscript Development and Review

Event	Timeline	Procedures	Responsibilities
Formation of writing team (see Section 19.2.5)	Approximately 4 months (16 weeks) before anticipated primary completion date or closed to follow-up date (whichever comes first)	• Notify CTS and protocol chair of upcoming closure • Remind protocol chair of timeline and need to designate a writing team • Hold pre-closure conference call(s) to include discussion of writing team formation and agree on communications plan (e.g., whether an executive summary or lay summary is needed, how sites/participants are to be notified)	Protocol statistician CTS Protocol chair, CTS
Finalization of statistical analysis plan	3 months (12 weeks) before anticipated primary completion date or closed to follow-up date (whichever comes first)	• Update/finalize the statistical analysis plan prior to initiation of final analyses	Protocol statistician, writing team chair and other members
Primary completion date or closed to follow-up date (whichever comes first); final data entry period begins	Day 0	• Notify CTS & Publications Coordinator	Protocol statistician
Receipt of final analysis report by protocol chair/writing team chair	5-6 months (20-24 weeks) after primary completion/closed to follow-up date	• Submit primary analysis report to Writing Team/Protocol Team Chair (any additional analyses needed will be provided in a timely manner so that the overall timeline is not adversely affected) • Notify CTS and Publications Coordinator that the analysis report has been transmitted	Protocol statistician
Manuscript preparation begins; 3-month (12 week) clock starts	Writing period should take no more than 8 weeks after the protocol chair's receipt of the final analysis report, leaving at least 4 weeks for review by masthead authors, writing team, protocol team (including NIH, pharmaceutical company representatives, etc.) and incorporation of comments/ revisions	• Remind protocol chair/writing team chair of manuscript submission deadline • Oversee timely completion of manuscript and adherence to timelines • Determine number and order of masthead authors • Develop full manuscript within 8 weeks • Distribute for review by team/authors/sponsor/site IoRs/pharmaceutical representatives and incorporate comments within 4 weeks • Begin compilation of the appendix of contributors	CTS or publications coordinator Protocol chair Protocol chair/writing team chair and other members Protocol chair/writing team chair and CTS

Table 19-2. Timeline for Development and Review of Primary Manuscripts, including Timetable for Writing Team Formation and Manuscript Development and Review

Event	Timeline	Procedures	Responsibilities
Manuscript submission for IMPAACT review (with lay summary, if needed)	12 weeks after analysis report provided to writing team	• Submit manuscript (with lay summary, if required) to publications coordinator (impaact.pubscoord@fstrf.org) indicating protocol number, primary/second manuscript, and to which journal the team will be submitting, if known: – If submitting to an Open Access journal, notify the publications coordinator for determination of Open Access fee coverage (see Section 19.11 for more information)	Writing team chair
		• Forward manuscript to IMPAACT Publications Group and relevant SC chair (if applicable) for review, with notification to the writing team chair	Publications coordinator
		• Confirm appropriate appendix of contributors and inclusion of Network and NIH acknowledgements	Publications coordinator
IMPAACT review complete (unless revision/re-submission required)	10 business days after submission for IMPAACT review	• Forward review comments and approval (or resubmission request) to writing team chair	Publications coordinator
		• If manuscript is approved, address reviewer comments and proceed with next step	Writing team chair
		• If approved with revision and resubmission requested, submit response and revised manuscript within 4 weeks to publications coordinator	
		• If disapproved, submit a revised manuscript within 8 weeks (substantial changes to be agreed upon by authors, protocol team (including pharmaceutical company representatives, if applicable), primary reviewer, and IMPAACT Publications Group chair)	
IMPAACT-approved primary manuscript submitted to journal	Within 4 weeks of IMPAACT approval	• Submit manuscript to journal and send copy to publications coordinator	Writing team chair
		• Ensure authors' disclosure of potential conflicts of interest as required by journal policy	
		• See Section 19.5 for additional guidance related to journal submission and procedures for various outcomes	

Table 19-2. Timeline for Development and Review of Primary Manuscripts, including Timetable for Writing Team Formation and Manuscript Development and Review

Event	Timeline	Procedures	Responsibilities
Acceptance for publication	Following journal submission	• Communicate outcome of submission to publications coordinator	Writing team chair
		• Ensure publishing agreement allows the paper to be posted to PubMed Central, in accordance with NIH policy, prior to signing the journal publication agreement (or similar copyright transfer agreement)	
		• Ensure authors' disclosure of potential conflicts of interest as required by journal policy	
		• 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 the publications coordinator	Writing team chair
		– submit manuscript to PubMed Central via the NIHMS on behalf of the corresponding author and supply the author with a NIHMS ID	Publications coordinator
		– approve the release and PubMed Central formatting of manuscript upon receipt of the email notification from NIHMS	Lead/corresponding author
Note: For more information on study closure procedures, refer to Section 14. The impaact.pubscoord@fstrf.org address should be used for all communication with the publications coordinator			

Table 19-3. Timeline for Development and Review of Secondary Manuscripts, including Timetable for Writing Team Formation and Manuscript Development and Review

Event	Timeline	Procedures	Responsibilities
Determination of secondary analyses, secondary writing teams, prioritization and timelines	Within eight weeks after final primary analysis report is received by the protocol chair	Submit list of secondary analyses specified in the protocol, newly planned analyses, and potential secondary manuscripts to the publications coordinator List should include: • Proposed writing team chair and brief title and description of each manuscript • List and status of laboratory samples and assay results required • Expected timeline for analysis completion, considering the steps outlined above for primary manuscripts • Where necessary, IMPAACT Publications Group guidance will be sought on prioritization of secondary analyses/manuscripts and/or which analyses may need to be completed without SDMC support • Monitor adherence to timelines; update as necessary	Protocol chair Protocol chair and statistician Protocol chair, CTS, and publications coordinator
Writing team formation (see Section 19.2.5)	May vary	• Form writing team • Notify publications coordinator of writing team chair	Protocol chair/ writing team chair
Preparation of statistical analysis plan	May vary	• Define analysis plan prior to initiation of data analyses	Protocol statistician, writing team chair, and other members
Receipt of final secondary analysis report by protocol chair/writing team chair	May vary based on prioritization and data availability (e.g., completion of lab assays)	• Submit analysis report to writing team/protocol team chair • Notify CTS and publications coordinator that the analysis report has been transmitted	Protocol statistician

Table 19-3. Timeline for Development and Review of Secondary Manuscripts, including Timetable for Writing Team Formation and Manuscript Development and Review

Event	Timeline	Procedures	Responsibilities
Manuscript preparation begins; 3-month (12 week) clock starts	Writing period should take no more than 8 weeks after the protocol chair's receipt of the final analysis report, leaving at least 4 weeks for review by masthead authors, writing team, protocol team (including NIH, pharmaceutical company representatives, etc.) and incorporation of comments/ revisions	• Remind protocol chair/writing team chair of manuscript submission deadline • Oversee timely completion of manuscript and adherence to timelines • Determine number and order of masthead authors • Develop full manuscript within 8 weeks • Distribute for review by team/authors/sponsor and incorporate comments within 4 weeks • Begin compilation of the appendix of contributors	CTS or publications coordinator Protocol chair Protocol chair/writing team chair and other members Protocol chair/writing team chair and CTS
Manuscript submission for IMPAACT review (with lay summary, if needed)	12 weeks after analysis report provided to writing team	• Submit manuscript (with lay summary, if required) to publications coordinator (impaact.pubscoord@fstrf.org) indicating protocol number, primary/second manuscript, and to which journal the team will be submitting, if known: – If submitting to an Open Access journal, notify the publications coordinator for determination of Open Access fee coverage (see Section 19.11 for more information) • Forward manuscript to IMPAACT Publications Group and relevant SC chair (if applicable) for review, with notification to the writing team chair • Confirm appropriate appendix of contributors and inclusion of Network and NIH acknowledgements	Writing team chair Publications coordinator Publications coordinator
IMPAACT review complete (unless revision/re-submission required)	See Table 19-2	• See Table 19-2	See Table 19-2
IMPAACT-approved secondary manuscript submitted to journal	See Table 19-2	• See Table 19-2	See Table 19-2
Acceptance for publication	See Table 19-2	• See Table 19-2	See Table 19-2
Note: For more information on study closure procedures, refer to Section 14. The impaact.pubscoord@fstrf.org address should be used for all communication with the publications coordinator			

Table 19-4. Timeline for Development and Review of Manuscripts from DACS and NWCS, including Timetable for Writing Team Formation and Manuscript Development and Review

Event	Timeline	Procedures	Responsibilities
DACS or NWCS submitted and approval based on availability of data/ specimens for use by investigators outside of the protocol team (See Section 15)	Unless otherwise determined by the protocol team and MOG, one year after protocol team confirmation of secondary analyses to be completed and published by the team	• Once the study data are openly available for use by investigators outside of the protocol team, proposals for use of data and specimens are submitted via a DACS or NWCS and reviewed as described in Section 15	Proposing investigators (may be protocol team members or investigators outside of the team)
Writing team formation	May vary	• Form writing team • Notify publications coordinator of writing team chair	Writing team chair
Preparation of statistical analysis plan	May vary	• Define analysis plan prior to initiation of data analyses	Statistician, writing team chair, and other members
Receipt of final secondary analysis report by protocol chair/writing team chair	May vary based on prioritization and data availability (e.g., completion of lab assays)	• Submit analysis report to writing team/ protocol team chair • Notify CTS and publications coordinator that the analysis report has been transmitted	Statistician
Manuscript preparation begins; 3-month (12 week) clock starts	Upon receipt of analysis report; timeline same as specified above for primary and secondary manuscripts	• See Table 19-2	See Table 19-2
Manuscript submission for IMPAACT review (with lay summary, if needed)	See Table 19-2	• See Table 19-2	See Table 19-2
IMPAACT review complete (unless revision/re-submission required)	See Table 19-2	• See Table 19-2	See Table 19-2
IMPAACT-approved secondary manuscript submitted to journal	See Table 19-2	• See Table 19-2	See Table 19-2
Acceptance for publication	See Table 19-2	• See Table 19-2	See Table 19-2
Note: For more information on study closure procedures, refer to Section 14. The impaact.pubscoord@fstrf.org address should be used for all communication with the publications coordinator			

19.2.5 Formation of Writing Team

For primary and secondary manuscripts, the protocol chair is responsible for designating writing team chair and members, which typically include the protocol chair or co-chairs, vice-chair(s), statisticians, clinical trials specialists, and other protocol team members, e.g., immunologist, virologist, pharmacologist, or other content expert(s), as appropriate. It is understood that others (e.g., protocol team members, etc.) may contribute to the manuscript as needed; however, the writing team is responsible for developing a complete manuscript.

The writing team for the primary manuscript is typically designated at the time of the pre-closure conference call; if a study is prematurely terminated such that a pre-closure conference call is not held according to the planned timeline, the writing team will be formed as soon after study closure as is feasible.

The writing teams for secondary manuscripts are typically designated within 6 months after receipt of the primary analysis report by the protocol chair. Specifically, the process of developing the list of proposed secondary analyses (new or specified in the protocol), potential manuscripts and writing teams is expected to begin when the primary analysis report is received by the protocol chair and be completed within 6 months. As noted above, the secondary analyses must be prioritized by the protocol team (or designated sub-group), with guidance from the IMPAACT Publications Group as needed, with identification of any analyses to be performed without SDMC support.

The protocol chair will communicate the writing team membership to the protocol team and the publications coordinator. The publications coordinator or CTS will provide the writing team chair the link to this section of the IMPAACT Manual of Procedures to ensure awareness of the expectations.

The formation of writing teams for DACSs, NWCSs, and DRs will vary but the process is generally as described in Table 19-4.

19.2.6 Preparation of Analysis Plan

For primary and secondary manuscripts, under the overall direction of the protocol chair, a statistical analysis plan is prepared for each writing team prior to the initiation of data analysis. For the primary manuscript, the statistical analysis plan should be updated/finalized approximately 12 weeks prior to closure to follow-up (or the primary completion date, whichever comes first). The senior protocol statistician is responsible for developing the analysis plan, in close collaboration with the other protocol statistician(s), the protocol chair, writing team chair and other writing team members. Although there may be many specific analyses mentioned in the analysis plan, the team should specify which components of the analysis are necessary to begin preparation of the parts of the manuscript describing the findings and this must be agreed to by the writing team chair and the statisticians. Text describing the background, study design, and other trial aspects should ideally be drafted while data analysis is underway.

The following components of the analysis constitute a core set of information that should be sufficient to begin describing the study findings in the manuscript:

- Participant accrual information
- Participant retention and completeness/status of follow-up
- Baseline characteristics
- Major outcome measures
- Safety/toxicity outcomes

The writing team may decide to expand this list, as appropriate; any additions should be specified in the analysis plan.

Note that not all analyses must be completed before beginning manuscript preparation (e.g., analyses of secondary outcome measures could be completed while the manuscript is in preparation). Supplementary information may also be sent during the writing period; however, manuscript development should proceed/continue once the core materials, and any agreed-upon additions, have been sent to the writing team by the SDMC.

If the team has not prepared an analysis plan, or if the analysis plan does not specify which components comprise the information necessary to begin manuscript preparation, then the above core set will be the default.

The preparation of analysis plans for DACSs, NWCSs, and DRs will vary but the process is generally as described in Table 19-4.

19.2.7 Completion of Analysis and Manuscript Preparation

For primary and secondary manuscripts, SDAC (or the non-SDAC statistician where applicable) will notify the publications coordinator and CTS upon completion of the required (core) analyses and transmittal to the writing team. The publications coordinator will notify the writing team chair that a final manuscript draft should be submitted for IMPAACT review within 12 weeks of receipt of the analysis report. The remaining analyses specified in the analysis plan, as well as others that may become important once the results become known, may be completed and sent to the writing team for inclusion in the manuscript during the writing period.

SDAC, NIH, and pharmaceutical company protocol team representatives are responsible for ensuring that any necessary reviews internal to their respective institutions are completed well within this time frame.

The completion of analysis and manuscript preparation for DACSs, NWCSs, and DRs will vary but the process is generally as described in Table 19-4.

19.3 Tracking of Manuscript Preparation

The guidelines and procedures outlined in this section apply to primary and secondary manuscripts as well as manuscripts developed from DACS or NWCS. Timelines may vary for DRs.

If the publications coordinator does not receive a final draft manuscript within 12 weeks following distribution of the final analysis report for the primary analyses by the SDMC, the publications coordinator will query the protocol chair and writing team for an explanation and proposed new timeline in writing. Requests for extensions must be approved by the IMPAACT Publications Group chair.

Further delays without sufficient justification may result in replacement of the writing team chair, as determined by the protocol chair (if different from the writing team chair) and the Publications Group chair in consultation with other members and endorsed by the SLG. The new writing team chair will be given a reasonable amount of time to complete the manuscript.

19.4 IMPAACT Manuscript Review Process

Manuscripts based on IMPAACT data must be reviewed and endorsed internally prior to journal submission. The writing team chair must submit a final draft, the lay summary (if applicable), appendix of contributors, Network and NIH acknowledgements, and the name of the journal targeted for submission to the publications coordinator to initiate the review process. The publications coordinator will review the submission to ensure that all applicable materials are included. The publications coordinator will submit the draft to the Publications Group, with a copy to the relevant SC chair. A primary reviewer is assigned by the Publications Group chair to review the manuscript in detail and determine whether to endorse it for journal submission. The primary reviewer may be a member of the Publications Group, a SC chair or vice chair, a member of the IMPAACT SLG, or another reviewer with specific expertise in the topic area.

The primary reviewer and Publications Group have 10 working days from receipt of the manuscript in which to comment. Comments are sent to the publications coordinator, who will compile and forward comments to the submitting author at the end of the comment period. All Publications Group members are not required to comment, but forfeit their right to do so after 10 days. The review will result in one of the following outcomes:

- Endorsed for journal submission with or without comments for author consideration; no further review required
- Revision and re-review required with comments to be addressed
- Disapproval

Endorsement for submission must be obtained before the manuscript may be submitted to a journal. If the manuscript is endorsed for journal submission with reviewer comments, the writing team will address those comments as appropriate and then proceed with preparation for submission.

If revision and resubmission is requested, a response and revised manuscript must be submitted by the writing team chair to the publications coordinator within four weeks of receipt of the review comments. Substantial changes must be agreed upon by the writing team, masthead authors, and protocol chair and may require re-review and sign-off by the pharmaceutical company or other sponsors/collaborators prior to resubmission for Publications Group review.

If disapproved, the publications coordinator will arrange for a discussion of potential next steps by the primary reviewer, Publication Group chair, writing team chair, and other writing team members, as needed. If agreement cannot be reached, the matter may be referred to the SLG. It is generally expected that a revised manuscript will be re-submitted within eight weeks. Substantial changes must be agreed upon by the writing team, masthead authors, and protocol chair and may require re-review and sign-off by the pharmaceutical company or other sponsors/collaborators prior to resubmission to the publications coordinator for Publications Group review.

Review of Manuscripts from Laboratory Projects

Manuscripts from IMPAACT laboratory projects must undergo IMPAACT review as described above; however, for these manuscripts, the LC PI or designee will serve as the primary reviewer.

19.5 Journal Submission

The final manuscript is submitted to the journal selected by the writing team chair in consultation with the protocol chair, and a copy is sent to the publications coordinator.

If a journal requests a statement about access to data, use the following:

> *"The data cannot be made publicly available due the ethical restrictions in the study's informed consent documents and in the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network's approved human subjects protection plan; public availability may compromise participant confidentiality. However, data are available to all interested researchers upon request to the IMPAACT Statistical and Data Management Center's data access committee (email address: sdac.data@fstrf.org) with the agreement of the IMPAACT Network."*

Revisions Comments from the journal reviewers should be handled at the writing team level. If significant changes are required, the writing team chair is responsible for notifying the publications coordinator, who will work with the Publications Group chair to determine if additional IMPAACT review is required.

Rejections If the manuscript is rejected, the writing team chair must inform the publications coordinator of future plans for the manuscript. Generally, manuscripts should be resubmitted within 8 weeks, unless additional major analyses are required. The writing team chair must circulate the revised manuscript to the protocol chair and masthead authors for sign-off prior to resubmission. In addition, if there are substantive changes (e.g., differences in the conclusions or findings described), re-review by the protocol team, pharmaceutical companies, and other sponsors/collaborators is required, and a copy of the reviewers' critique and the revision should be sent to the publications coordinator for transmittal to the Publications Group, with re-review and approval by the primary reviewer required prior to re-submission.

Accepted manuscripts Upon acceptance of the manuscript for publication by the journal, the writing team chair is responsible for providing an electronic copy of the manuscript to the publications coordinator, masthead authors, and the protocol team.

If the manuscript is being published in a journal that does not deposit final published articles in PubMed Central, the writing team chair should follow the Public Access Policy described in Section 19.8, below.

19.6 Authorship

The guidelines and procedures outlined in this section apply to primary and secondary manuscripts as well as manuscripts developed from DACS or NWCS as well as abstracts.

19.6.1 Guidelines for Authorship

The masthead should include those individuals who have made substantial intellectual contributions to the specific manuscript, as defined in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (http://www.icmje.org/icmje-recommendations.pdf):

"Authorship credit should be based only on:

- *Substantial contributions to conception and design; or 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.*

In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.

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. These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work. The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion #s 2 or 3. Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript."

19.6.2 Decision for Authorship and the Author Order

The list and order of names on the masthead is to be determined by the writing team chair as the manuscript is in preparation and finalized by the time the manuscript is ready for submission; the decision should be a reflection of individuals' intellectual contributions. The masthead for authorship of an article may be limited to journal guidelines, which may allow a range of 6 to 20 names. When authorship must be limited, it is preferable for each organization involved to be represented by a single author. The first author of the manuscript is usually the writing team chair.

It is recommended that site investigators at sites that enrolled large numbers of participants or IMPAACT investigators with specific expertise in the topic of the manuscript be invited to participate on the writing team early in the analysis plan development process so that they have the opportunity to meet these authorship criteria. Specifically, for studies that enrolled participants from fewer than six institutions, one investigator from each institution contributing study participants may be considered for masthead authorship. For studies involving more than six institutions, institutions with high participant enrollment may have one investigator considered for masthead authorship. Site representation may also be determined based on the number of participants included in a specific sub-analysis. The address of each co-author should reflect his/her own 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 team may consider developing an alternative plan for allowing masthead authorship by investigators from participating sites. This plan should be presented to the Publications Group chair.

In instances where study work is completed or substantially conducted at one institution and a masthead 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.

The relative roles of each member of the writing team will be determined as soon as the writing team is formed. Any disputes regarding study authorship or position on masthead should be addressed first with the writing team chair and protocol team chair. Decisions concerning authorship may be appealed, if necessary, to the Publications Group chair.

19.6.3 Appendix of Contributors

In addition to the authors listed on the masthead, study-related primary and secondary manuscripts must include an appendix acknowledging contributors who were not listed on the masthead. Other contributors (e.g., protocol team members who are not masthead authors, site investigators/staff) will be listed in the appendix. All participating site institutions enrolling participants will be acknowledged in the article and generally listed in order according to the number of participants enrolled. The listing will include up to four persons per participating institution, including SDAC, DMC, LC, Operations Center, sponsoring NIH institutes, and industry or other collaborators as well as the participating sites. The listing will be compiled by the writing team chair, protocol team chair, and CTS. The Publications Coordinator will confirm that there is an appropriate appendix of contributors upon submissions for IMPAACT review.

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

If no appendix of contributors is allowed by the journal, the acknowledgements should include those specified in this section, with the number of individuals cited per institution to conform to the journal's specifications.

In general, this policy to acknowledge contributors applies to any Conference Presentation Materials (as described further in Section 19.9).

19.7 Acknowledgements

19.7.1 Network and NIH Acknowledgements

The IMPAACT Network and the specific protocol number should be included in the title and body of the manuscript (e.g., IMPAACT XXXX).

The grant acknowledgment and disclaimer on behalf of NIH should be as follows:

> *"Overall support for the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) was provided by the National Institute of Allergy and Infectious Diseases (NIAID) with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH), all components of the National Institutes of Health (NIH), under Award Numbers UM1AI068632 (IMPAACT LOC), UM1AI068616 (IMPAACT SDMC) and UM1AI106716 (IMPAACT LC), and by NICHD contract number HHSN275201800001I. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."*

Any publications associated with a DACS, NWCS, or DR should include grant acknowledgement of IMPAACT and disclaimer of NIH, as described above.

19.7.2 Other Acknowledgements

If the work represented by the manuscript was directly supported by other sponsors, they should be acknowledged accordingly and in keeping with the terms of any applicable CTAs, MOUs, or other collaboration and sponsor agreements. For example, if study products were supplied by the manufacturer free of charge for use in the study, this should be acknowledged. It is the responsibility of the writing team chair and protocol team chair to ensure appropriate acknowledgement of contributors, sponsors, and collaborators.

19.8 Public Access Policy

The IMPAACT Network will comply with the NIH Public Access Policy. The complete information on this policy is available at the following website: http://publicaccess.nih.gov/index.htm. The Public Access Policy requires that all manuscripts accepted for publication that are based on studies with NIH funding be submitted to the PubMed Central digital archive, where they will be available to the public. The final, peer-reviewed manuscript accepted for journal publication is the version to be submitted.

Some journals have made arrangements with the NIH to submit manuscripts accepted for publication without any further required action by the authors. The list of these journals can be reviewed at the following website: http://publicaccess.nih.gov/submit_process_journals.htm. For manuscripts submitted to journals not on this list (not already complying with the Public Access policy), authors must inform the journal that the manuscript is subject to the Public Access Policy when submitting it for publication, and make sure that any copyright transfer or other publication agreement allows the final peer-reviewed manuscript to be submitted to NIH in accordance with the policy. When the final peer-reviewed manuscript has been accepted for publication, the author must send a copy of this version of the manuscript and a copy of the signed publication agreement (or similar copyright transfer agreement) to the publications coordinator, who will submit the manuscript to PubMed Central via the NIHMS on behalf of the corresponding author and supply the author with a NIHMS ID, copying the SDMC's

publications tracking group (cbar.pubs@sdac.harvard.edu). The lead author approves the release and PubMed Central formatting of manuscript when receiving the email notification from NIHMS.

The publications coordinator will follow up with authors on the status of manuscripts that have been approved for journal submission by the IMPAACT Publications Committee and will track the progress on journal submission, submission to PubMed Central and assignment of ID numbers.

19.9 Abstracts

Abstracts reporting results of IMPAACT studies or otherwise based on IMPAACT study data may not be presented at a conference or other public venue without IMPAACT Publications Group review and approval. Abstract authorship should generally follow the guidelines as included in Section 19.6, above. Prior to submission to the publications coordinator for this review, draft abstracts reporting study or study-related results must receive sign-off by the co-authors and the protocol team and undergo any necessary review by industry or other sponsors/collaborators as specified in the CTA or other third party agreement. If results of a sub-study are being reported, the protocol team (minimally, the protocol chair(s), protocol statistician(s), MO(s), and pharmaceutical representatives) should review the draft abstract. The writing team chair is responsible for ensuring that all applicable reviews are completed and approvals are obtained prior to conference submission.

Unless otherwise directed for conferences with a large number of abstracts expected, the writing team chair must submit the draft abstract to the publications coordinator at least 5 working days prior to the deadline for the abstract to be submitted to the conference organizer. If this is not feasible due to the need for last-minute data collection or analyses, the abstract should be submitted for review at the earliest possible time, and no later than two working days prior to the abstract submission deadline. If the data necessary to complete the abstract are not available within the designated time frame, an alternate review process may be determined by mutual agreement of the writing team and the IMPAACT Publications Group chair.

An IMPAACT review will be conducted by the Publications Group chair or a designated reviewer within 3 days of receipt unless agreed otherwise as noted above. Review outcomes and other comments will be compiled by the publications coordinator and then forwarded to the submitting author.

The corresponding author will inform the publications coordinator of acceptance of abstract and its number, if known, within 10 days of notification by the conference organizer and provide a copy of the final accepted version.

If the abstract is accepted and the protocol team determines that an executive summary, a site investigator letter, and/or participant letter are needed, these will be prepared and typically distributed to participating study sites at least 2 days in advance of the conference presentation; however, the terms of any NIH or conference embargo will take precedence. If NIH or the network leadership determines that a press release should be issued, its development and release will follow the procedures outlined in Section 6.

If an abstract is rejected by the conference organizer and the authors decide to revise and resubmit, it must undergo re-review by the protocol team and the IMPAACT Publications Group prior to resubmission if substantive changes are made.

Preparation of Conference Presentation Materials

If an abstract is accepted, the writing team chair/lead author must circulate the draft slides and/or poster to the protocol team (minimally, the protocol chair(s), protocol statistician(s), MO(s), CTS(s) and

pharmaceutical representatives), including NIH representatives and pharmaceutical industry and other collaborators, for review. Posters and slides do not need to be reviewed by the IMPAACT Publications Group. Use of the IMPAACT logo (available on the website, http://impaactnetwork.org/resources/templates.htm, or from the Operations Center) and appropriate contributors (Section 19.6.3) and acknowledgements (Section 19.7) are required on all abstract posters and presentations.

The accepted abstract will typically be sent to the PIs of all participating sites at least one day before conference presentation by the publications coordinator or CTS; however, the terms of any NIH or conference embargo will take precedence.

Within two weeks of the conference presentation, the writing team chair/lead author should send a copy of the final materials presented to the publications coordinator for posting on the IMPAACT website.

19.10 Communications Plans and Dissemination of Study Results

With input from the NIH sponsors and other collaborators, the protocol team (minimally, the protocol chair(s), protocol statistician(s), MO(s), CTS(s) and pharmaceutical representatives) is responsible for determining the appropriate plans and timing for communication of study results depending on the nature and status of the study, whether the findings may impact study participants or the standards of care for HIV-related treatment or prevention. This determination should be made around the time that the core analysis report is provided to the writing team and protocol chair by SDAC or before. The timing of development and implementation of the communications plan and materials may be dictated by a recommendation for early release of findings by the DSMB or Study Monitoring Committee overseeing the study. Study results may be shared with participating sites, sponsors, and collaborators through a number of means, including Executive Summaries, Site Investigator Summaries, Participant Letters, Lay Summaries, talking points, and question and answer documents.

19.10.1 Executive Summaries and Accompanying Materials

For Phase III studies and for certain other studies with results that could alter the standard of care for HIV infected or affected populations or influence the design or conduct of ongoing or future clinical trials, selected members of the protocol team, led by the protocol chair and statistician and including the vice chair(s), CTS(s), and MO(s), will prepare a draft Executive Summary based on the core analysis report (See Table 19-1). The primary purpose of an Executive Summary is to disseminate data generated from IMPAACT studies to site investigators, study participants, sponsoring industry collaborator(s), and key stakeholders in a timely fashion before or at the same time as they are released to the general public. The draft Executive Summary will be reviewed and agreed by the protocol team (minimally, the protocol chair(s), protocol statistician(s), MO(s), CTS(s), and pharmaceutical representatives), the IMPAACT Publications Group, and NIH before being distributed to participating investigators and others, and the terms of any NIH or conference embargo will take precedence.

The Executive Summary should be as concise as possible and summarize the final data analysis. The following information should be included:

- Abstract – a brief summary of the study design, hypotheses, conduct, and results
- Trial design – summary of the study design, including information such as the objectives, outcome measures, drug doses and schedule, eligibility, and important protocol changes
- Statistical methods – a summary of the original power and sample size calculations, information about interim monitoring, and methods used for analyses presented in the Executive Summary

- Study population – accrual information, demographics, any differences in baseline characteristics, and eligibility violations
- Results
- Conclusions/Implications

Members of the protocol team (noted above) will review the draft within 5 working days of receipt and provide comments to the protocol chair, or designated team member, for incorporation into a final draft. The draft must clearly state that the material is confidential and not for public distribution. Team members may not disseminate the results prior to release of the Executive Summary.

The CTS or publications coordinator will then forward the final draft Executive Summary to the Publications Group and the relevant SC chair for review. These reviews should be concurrent and occur within 5 working days. An Executive Summary cannot be disseminated until it has been through this IMPAACT review process and approved by the Publications Group and MOs.

In the event of a disagreement between the reviewers and the protocol team, other members of the Publications Group should be consulted.

If an urgent Executive Summary is required, this timeline may be altered based on the circumstances, as approved by the Publications Group chair.

Typically, an Executive Summary will be accompanied by other documents reflecting the same messages in an appropriate format; these may include a Participant Letter, talking points, or question and answer documents intended primarily for use by participating study sites. These documents will be developed and reviewed by members of the protocol team in parallel with the Executive Summary; consistency with the final version of the Executive Summary will be confirmed.

Once the Publications Group and MO(s) review the Executive Summary, then it and any accompanying documents will be disseminated, with instructions for sites. The minimum electronic distribution list is as follows:

- Investigators of Record at participating sites
- Protocol team members, including the MOs
- Network chair, vice chair, LC PI, SDMC PI, and Operations Center Director
- Relevant SC chair
- Industry sponsor(s), if the company's sponsorship/support is listed on the protocol document but there is no industry representative on the protocol team distribution list

A copy will be sent by the CTS to DAIDS Regulatory Support Center for submission to the Food and Drug Administration for studies conducted under an IND held by DAIDS.

Final approved Executive Summaries and accompanying materials will be disseminated at least 48 hours prior (2 days) to release to the general public (e.g., issuance of a press release by the sponsor or presentation at a conference), with instructions to sites for notification of/submission to their IRBs/ECs and other regulatory entities. Participant Letters and other materials provided to participants must be approved by the site IRBs/ECs prior to use.

NIH has the authority to embargo any/all information in Executive Summaries and accompanying documents, Site Investigator Letters, Participant Letters, and press releases, until information is made public (i.e., abstract presentation or manuscript publication).

19.10.2 Lay Summaries

For all IMPAACT-related manuscripts that may have clinical relevance to study participants and communities, as determined by the writing team chair, a Lay Summary must be prepared unless the findings have been communicated to the sites and participants earlier, according to the communications plan agreed upon by the Protocol Team and MOG. Lay summaries would generally be expected for primary and secondary manuscripts in which the findings being reported may have a clear impact on clinical care. The lay summary should be submitted to the publications coordinator when the manuscript is submitted for review by the Publications Group. If no lay summary accompanies the manuscript and there is no explanation, the publications coordinator will request that the lay summary be prepared and submitted or an explanation provided. The manuscript will not be sent forward for review and endorsement until the lay summary or explanation has been submitted. If the explanation provided for not including a lay summary is deemed insufficient by the IMPAACT Publications Group chair, the writing team chair will be notified and asked to prepare the summary.

The writing team and protocol chair are responsible for developing the Lay Summary. The publications coordinator coordinates the review and approval of the summary by the ICAB chair. The CTS is responsible for dissemination of the approved summary to participating study sites and team members.

- The Lay Summary should be as concise as possible (ideally one page in length), written in 6th to 8th grade level language, and follow the outline provided in Figure 19-1.
- Once the summary is approved by the protocol chair and other team members, the writing team chair submits it to the publications coordinator along with the manuscript for review.
- The publications coordinator submits the summary to the ICAB chair (or designee) for review. A 10-day period is allowed for review of the lay summary, concurrent with the review period for the manuscript. If the substance of a publication changes after review, the author is responsible for updating the lay summary accordingly.
- After the manuscript and summary have been endorsed by the Publications Group and ICAB chair, respectively, the publications coordinator notifies the CTS for that protocol. The CTS will send the Lay Summary to the protocol team and participating study sites prior to or when the manuscript is accepted for publication, with the relative timing to be agreed upon by the protocol chair, medical officers, and other team members. The accompanying message will note that the findings in the lay summary are preliminary and may change as the study continues (if relevant) and that no public statements can be made about the information contained in the summary until the manuscript is published or abstract presented, and instructions regarding its intended dissemination will be provided. If the manuscript is not accepted, the lay summary will not be distributed.
- When the manuscript is published or abstract is presented, the lay summary will be posted on the protocol-specific and community pages of the IMPAACT website.

Figure 19-1. Lay Summary Components

- Protocol Number and Title
- Study Description: *purpose/goal of the study and why it is important, number and location of study participants, current status*
- Key Findings and Potential Implications: *no figures or tables to be included*
- Support: This study was supported by the US National Institutes of Health, National Institute of Allergy and Infectious Diseases, Division of AIDS, the National Institute of Child Health and Human Development, the National Institute of Mental Health and sponsoring drug company (insert name, if applicable).
- Authors and their affiliations

19.10.3 Press Release by Pharmaceutical, Biomedical Industry or External Collaborators

Review and issuance of press releases developed outside the IMPAACT Network (e.g., pharmaceutical, biomedical industry, or external collaborators) will follow the terms included in any applicable CTAs with DAIDS. A copy of the published press release should be sent to the Publications Coordinator.

19.11 Publication Costs

Through the Operations Center, IMPAACT will cover review fees and pages charges for primary and secondary manuscripts if they have been primarily funded by the network and properly credited to the network. Any additional author fees charged for approved manuscripts, including costs for publishing in an Open Access journal and charges for color figures, will covered on a case-by-case basis as determined by the Publications Group chair.

IMPAACT will not cover Open Access costs for publishing in journals that do not require Open Access. Authors submitting a request for IMPAACT to cover Open Access costs in a journal that requires Open Access (e.g., PLOS ONE), must provide justification for submitting to this type of journal. If the publication cost is for a color figure(s), provide justification for publishing in color.

Once confirmation is received that the IMPAACT Operations Center will cover the publication costs, the publications coordinator will provide the author with information for the invoice. Costs associated with ordering reprints will not be covered by IMPAACT and remain the responsibility of the author.

Publication costs for manuscripts resulting from NWCS and DACS will not be covered.