21 PUBLICATIONS REQUIREMENTS AND PROCEDURES

21.1 Overview, Key Principles, and Definitions

Publications in peer-reviewed journals and presentations at scientific conferences and to policy and advisory groups represent the most significant products of the Infectious Diseases Clinical Research Consortium (IDCRC). The results of IDCRC 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 the timely development and dissemination of high-quality products reporting the results of IDCRC studies, or otherwise using Consortium-generated data and biological specimens, and the expedited publication of information in the case of Public Health Emergencies.

REQUIREMENTS

The results of all completed IDCRC trials should be published in peer-reviewed journals. The results of primary and secondary objectives should be made public.

- All abstracts and manuscripts using IDCRC data or samples must be submitted to the IDCRC Collaborations and Publications Committee (CPC) and undergo the CPC review and clearance process prior to submission to a conference or journal.

- All abstracts and manuscripts referencing the IDCRC grant or funded with IDCRC funds must be submitted to DMID for review prior to publication.

- For manuscripts and abstracts related to data generated during studies of diseases classified as Public Health Emergencies (e.g. COVID-19) during any portion of the study there is no requirement for prior CPC review. Copies of these documents should be forwarded to the CPC for logging and appropriate public relations activities. DMID will require prior review before submission for publication.

- The results of the study (primary manuscript) must be submitted and accepted for publication prior to those of sub-studies and secondary manuscripts, unless otherwise approved by the CPC and the IDCRC Leadership Operations Center (LOC).

When possible, IDCRC publication procedures should be addressed in the terms of IDCRC-negotiated Clinical Trials Agreements (CTA), Memoranda of Understanding (MOU), or alternative agreements negotiated by the IDCRC 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 IDCRC Statistical and Data Science Unit (SDSU).

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

For interventional trials, results for all primary outcome measures must be entered into ClinicalTrials.gov in compliance with *NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information* 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. Additionally, these entries are required if a non-interventional study is entered into ClinicalTrials.com.

Protocol Chair Responsibilities

The protocol chair/co-chairs assume 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 the timeframe outlined below. The protocol chair/co-chairs oversee the designation of primary authors or the initial members of the writing team to draft manuscripts or abstracts; the writing team chair is then responsible for completion and submission for IDCRC review within the timeline specified below, with continued oversight by the protocol chair/co-chairs. The protocol chair/co-chairs will ensure that analysis and publication of secondary or sub-study results (Section 21.7, Ancillary Studies MOP 17.2) do not interfere with the analysis or publication of the primary study results and will work closely with the CPC to track the manuscript development progress and publication, and to address any concerns that may arise.

Table 21-1. 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, when a study is conducted in multiple stages and has a primary objective for each stage. For each IDCRC study, the primary manuscript must be submitted and accepted for publication prior to secondary and sub-study manuscripts unless otherwise approved by the CPC and the IDCRC LOC.
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 secondary research, i.e., analysis of specimens and/or data collected as part of a study but used for analyses not specified in the study protocol.
Abstract	Brief report of IDCRC study data prepared for submission to a conference; may be classified as a regular abstract or a late-breaker abstract.
IDCRC Collaborations and Publications	Group responsible for providing oversight to the review process for IDCRC manuscripts and abstracts on the behalf of the network prior to journal/conference submission.
Publications Coordinator	Individual designated by the CPC as responsible for logging and routing all manuscripts and providing official IDCRC publication data for reporting to DMID and other stakeholders.

Public Health Emergency	A disease or disorder that presents a public health emergency as determined by the Secretary of the Department of Health and Human Services (HHS) or circumstances of similar urgency as indicated by the Centers for Disease Control and Prevention (CDC). The CPC will have an expedited process for manuscripts of time-sensitive public health importance, for example during a pandemic when information is needed to guide decision-making.
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
Protocol team	The team members whose names appear in the protocol roster, which usually includes pharmaceutical/industry representatives and other study sponsors/collaborators.
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.
Tier 1 Manuscript	Primary IDCRC manuscripts describing important multi-site trials, for example NEJM submissions for ground-breaking IDCRC network-originated trials or trials with significant IDCRC involvement.
Tier 2 Manuscript	Primary manuscripts from single site projects.
Tier 3 Manuscript	Secondary manuscripts

21.2 Development and Review of Manuscripts

21.2.1 Development of Tier 1 and Tier 2 Primary Manuscripts

The timeline and process for development and review of Tier 1 and Tier 2 primary manuscripts are outlined in Table 21-1 and Table 21-2. The primary results manuscript should be submitted to CPC for review within 4 weeks of approval of CSR/FSR v1.0, approximately **seven months following study database (clinical and laboratory) lock.** This allows for timely reporting of study outcomes. This timeline assumes the following intermediate milestone estimates:

- 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.
- CSR/FSR v0.1 anticipated to be provided to protocol chair and writing team approximately 12-16 weeks after database lock.
- **Manuscript fully prepared and sent to all masthead authors** (those authors whose names appear at the top of the article at publication), protocol team members, corporate sponsors/collaborators to sign off, unless otherwise specified in the CTA or other third party agreement): **approximately 10 weeks after the protocol chair and writing team's receipt of the CSR/FSRv0.1** required for primary outcome analysis.
    - The timeline for review is 4 weeks.
- CSR/FSR v1.0 is approved approximately 6 months after final database lock.
- Manuscript submitted for IDCRC review: **4 weeks after the CSR/FSR v1.0** is approved.

21.2.2 Secondary Manuscripts

The timeline and process for development and review of secondary manuscripts are outlined in Table 21- 3. The protocol team begins developing the list of potential secondary analyses, potential manuscripts and writing teams as the study progresses, with a timeline to produce these manuscripts after the primary manuscript.

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 timeframe. 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 relevant TFLs are submitted to the writing team chair, the draft manuscript is expected to be submitted to the publications coordinator for IDCRC 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 and accepted for publication prior to those of secondary (or sub-study) manuscripts, unless otherwise approved by the IDCRC CPC Chair (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 CPC to track the manuscript development progress and to address any concerns that may arise.

The IDCRC review process for secondary manuscripts is the same as for Tier 2 primary manuscripts.

21.2.6 Non-Protocol-Related Publications

For IDCRC publications that are not related to specific protocols (for example, laboratory publications that describe a validation process that used samples from multiple protocols), the Primary Author is responsible for managing and ensuring that all necessary reviews of the publication have occurred prior to submitting it to DMID review, including Co-Author(s) (always) and Product Developer(s) (if applicable, due to an MTA). The Publications Coordinator will document that the required reviews have taken place.

21.2.7 Formation of Writing Team

For primary and secondary manuscripts, the protocol chair/co-chairs are responsible for working with the study team to designate writing team chair and members, which typically include the protocol chair or co- chairs, statisticians, clinical trials specialists, and other protocol team members (e.g., LG and other operating roles (including LOU and SDSU representatives), endpoint labs, immunologist, virologist, pharmacologist, or other content experts), as appropriate. It is understood that others (e.g., protocol team members) may contribute to the manuscript as needed; however, the writing team is responsible for developing a complete manuscript.

The primary authors are normally designated early in the process, ideally during the study. The rest of the writing team for the primary manuscript is typically designated prior to study closure or as soon after study closure as is feasible. The writing team can also begin to compile the appendix or additional contributors (study group and study team).

The protocol chair will communicate the writing team membership to the protocol team and the publications coordinator. The CPC or Protocol Team Protocol Specialist (PS) will provide the writing team chair a link to this section of the IDCRC Manual of Procedures to ensure awareness of the expectations.

21.2.8 Completion of Analysis and Manuscript Preparation

For primary and secondary manuscripts, the protocol specialist will notify the publications coordinator through the COU upon completion of the required (core) TFLs and delivery to the writing team. A final manuscript draft should be submitted for IDCRC review within 12 weeks of receipt of the TFLs (unless writing team identifies additional analyses needed for the primary manuscript). 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.

It is the responsibility of the IDCRC to ensure that NIH, pharmaceutical companies, and other collaborators are provided the manuscript within the prescribed timeframe. The IDCRC will communicate the deadlines for submission of reviews, including reminders as appropriate, to ensure that reviews are completed within the defined timeframe. In special circumstances where the review timeline is necessarily compressed, the need for an expedited review will be communicated in advance if possible.

21.2.9 Publication of Preliminary Data

With appropriate DMID and IDCRC approvals, preliminary results of the study may be presented prior to the completion and submission of the final clinical study report (CSR). These 'top-line' data may be used for various scientific activities, such as conference abstracts and presentations at scientific meetings, provided that such a release is permitted by the protocol and any other study agreements (e.g. CTA)**.** Examples include:

- Presentations including top-line data before the CSR is completed: This is likely most important for high impact studies and important meetings, and would be limited to abstract presentations, and scientific presentations. These materials would be subject to DMID review and approval if necessary, and to IDCRC review per section 21.13 (Abstracts & Posters).
- Publications or presentations based upon data from completion of the primary CSR: Some studies have many objectives; in order to expedite critical results, it may be prudent to define an interim CSR**,** defined by DMID as the document containing the majority (minimum of primary and secondary) of the study endpoints, and then define what can be included in a CSR addendum, defined as a document that includes data or analysis of study endpoints not presented in an interim CSR..
- Early release publications require the review and approval of DMID and would normally include the IDCRC publication review process unless the publication relates to data generated during studies of diseases classified as Public Health Emergencies (e.g. COVID-19) during any portion of the study.

21.3 Tracking of Manuscript Preparation

The guidelines and procedures outlined in this section apply to primary and secondary manuscripts.

If the publications coordinator does not receive a final draft manuscript within 12 weeks following distribution of the TFLs for the primary analyses by the SDCC, 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 IDCRC LG Representative or CPC KFC 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 CPC chair, in consultation with other members and endorsed by the LOC. The new writing team chair will be given a reasonable amount of time to complete the manuscript.

21.4 IDCRC Manuscript Review Process

Manuscripts related to research funded by the IDCRC, or based on IDCRC data or samples must be reviewed internally prior to journal submission (with exceptions for manuscripts related to data generated during studies of diseases classified as Public Health Emergencies (e.g. COVID-19) during any portion of the study, which require expedited review). The writing team chair must submit a final draft, appendix of contributors, Network and NIH acknowledgements, and the name of the journal targeted for submission to the CPC to initiate the review process.

The CPC will send it to the Chair of the appropriate Expert Working Group for primary review. That individual will either review the manuscript, select someone else from within the EWG to perform the primary content review, or indicate to the CPC Chair that reviewer (s) must be sought from another source. The manuscript will be forwarded to NIAID for review simultaneously with the CPC review process.
Statistical review may be requested if needed, but only if the SDSU was not part of the writing team.

The CPC Chair may request one or two content reviewers, depending on the manuscript.

- Tier 1 manuscripts, defined as primary IDCRC manuscripts describing important multi-site trials (for example, NEJM submissions for ground-breaking IDCRC network-originated trials or trials with significant IDCRC involvement) will normally require one content reviewer.

- Tier 2 manuscripts, defined as primary manuscripts from single site projects, will require one content reviewer.

- Tier 3 manuscripts, defined as all secondary manuscripts, will normally require one content reviewer unless the CPC chair determines that additional reviewers would be required. At any point, for any of the above types of manuscripts, a reviewer may request an additional review by a member of the LOC.

For Tier 1 and Tier 2 manuscripts:
- The review will be returned to the author within 5-7 business days.
- Statistical review may be requested, but only if the SDSU was not part of the writing team.
- The reviewer may request that the revised manuscript be returned for a second review after revisions are incorporated.
- If this is the case, the reviewer must return the revised manuscript within 5 business days.
- If the reviewer does not ask to see the changes, the author may, but is not required to, accept the suggested revisions. At that point, if DMID has reviewed the manuscript, then the primary author will be able to submit the manuscript to the agreed upon journal, providing a copy to the CPC Publications Coordinator for tracking.
- If the journal requires substantial revisions prior to publication, the author may be required to resubmit to the CPC and NIAID for review.

For Tier 3 (secondary manuscripts):
- There will be up to two content reviewers as well as a DMID review.
- Statistical review may be requested, but only if the SDSU was not part of the writing team.
- If the review requires changes, the primary authors will be given 5-7 business days to make the changes and resubmit to the CPC. Both the CPC and the primary reviewers will evaluate the revised draft.

- Changes requested by reviewers and/or NIAID will be sent to the lead author, who will take responsibility for subsequent revisions. Once those changes are made, the manuscript will be forwarded to the CPC and NIAID for review.
- If approved, the primary author will be advised to submit the manuscript to the agreed upon journal. If the journal requires substantial revisions prior to publication, the author may be required to resubmit to the CPC and NIAID. Secondary manuscripts will follow the timeline above for Tier 2 Primary Manuscripts.

As noted in Section 21.1, manuscripts and abstracts related to data generated during studies of diseases classified as Public Health Emergencies (e.g. COVID-19) during any portion of the study requiring urgent expedited communication of research results to the public, will have no requirement for prior CPC review, although DMID/NIAID prior review will be required. Copies of these documents should be forwarded to the CPC for logging and appropriate public relations activities.

Following acceptance by a journal or scientific meeting, the primary author will share the accepted manuscript/abstract with the CPC, members of the writing group and NIAID, prior to publication or presentation. IDCRC Communications and the CPC will work with NIAID and the lead author's institution in developing any related press releases.

Publication policies and timelines will be evaluated and modified as needed annually.

21.5 Review of Manuscripts from Laboratory Projects

Manuscripts from laboratory studies involving IDCRC study data, subjects, or samples, either papers from ancillary studies totally funded by the LOU or IDCRC-funded efforts led by the LOU, must follow normal IDCRC review processes for secondary manuscripts, with the following exceptions:

- The LOU PI, or designee (e.g. if PI is an author) will serve as the primary reviewer.
- A second reviewer will be named from the Laboratory Sciences Committee, or the Chair may determine that a statistical review should take place due to significant statistical analysis or novel analysis methods.

The Chair of the Laboratory Sciences Committee may request a third review from the EMT if appropriate.

21.6 Review of Manuscripts from Statistics and Data Science Unit Projects

Manuscripts from statistical studies involving IDCRC study data, subjects or samples emanating from the SDSU, either papers from ancillary studies totally funded by SDSU or IDCRC funded efforts led by SDSU, must follow normal IDCRC review processes for secondary manuscripts, with the following exceptions:

- The SDSU Director, or designee (e.g. if PI is an author) will serve as the primary reviewer.
- A study PI if not an author should serve as the second reviewer.

The SDSU Director may request a third review from the EMT if appropriate.

21.7 Review of Manuscripts from Ancillary Studies

Ancillary studies are investigations which are not part of IDCRC protocols but use all or a subgroup of the subjects, samples, or data. For publications from ancillary studies, the

expectations and procedures for manuscript development and review are the same as for secondary manuscripts.

Two reviewers are required. It is recommended that one review be a statistical review from the statistician on the protocol team, and the second reviewer be the original study investigator.

21.8 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 CPC.

Revisions: If the journal requires substantial revisions prior to publication, the author may be required to resubmit to the CPC and NIAID for review. The protocol team chair should be consulted regarding the need for these additional reviews.

Rejections: If the manuscript is rejected, the writing team chair must inform the CPC 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 CPC, 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 primary reviewer, protocol team, DMID, and other sponsors/collaborators is required.

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 publication's 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 (see 21.8 below):

21.9 Authorship

The guidelines and procedures outlined in this section apply to primary and secondary manuscripts as well as abstracts.

21.9.1 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."

21.9.2 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 early as possible in the preparation of the manuscript, and finalized by the time the manuscript is ready for submission. The decision should reflect individuals' intellectual contributions. All individuals who have made author-level contributions per ICMJE standards should be included in masthead or study group author lists for IDCRC manuscripts.

The masthead for authorship of an article may be limited by journal guidelines. The writing team should confirm with the journal the specific limits for masthead and study group authorship.

It is recommended that site investigators at sites that enrolled large numbers of participants or IDCRC 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 the authorship criteria. Inclusion of appropriate junior investigators is encouraged.

Additional authorship considerations include:

- When authorship must be limited, it may be appropriate to limit each organization involved to a single author depending upon the number of sites and the number of authors permitted.
- The first author or the senior author of the manuscript is usually the writing team chair.
- The writing team chair may elect the senior author position and name a more junior colleague for the first author position.
- A longer list will be required for the appearance of the publication in PubMed.
- The listing may also include other participants who satisfy the Uniform Requirements, such as representatives of the SDSU, LOU, FHI360 protocol specialists, DMID, EMMES, and industry or other collaborators.

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 CPC chair, and may be referred by the CPC Chair to the LOC.

When a site withdraws from a study prior to any enrollments, if the site was not involved in protocol development for the study or the source of any other substantial contribution, the writing team may determine that the site should not be offered authorship on any manuscript resulting from that study. All relevant circumstances should be considered in this decision. The decision of the writing team may be appealed to the Collaborations and Publications Committee.

21.9.2.1 Authorship for Trainees and Junior Faculty

Trainees and junior faculty often play substantial roles in clinical trial activities. Every effort should be taken during protocol development to identify authorship opportunities for these individuals. Multisite studies are often the most challenging, as authorship is often limited to only 1-2 authors per site. In these situations, the following categories of authorship can be considered:

1. **Authorship, masthead level**: Since only masthead level authorship is used to calculate h-index and other metrics of authorship, masthead level authorship should recognize critical contributions to study conduct. Trainees and junior faculty who contribute time assisting in protocol development, trial implementation, data analysis, and manuscript writing should be considered a priority for masthead level authorship.

2. **Authorship, as part of the study-team**: Many authors contribute substantially to the conduct of a study, but do not rise to the level of masthead level authorship. These individuals should be identified as part of the XX-XXXX study team. Typically, these individuals will have their authorship recognized by PubMed and these manuscripts are more readily referenceable on CV's and biosketches.

3. **Contributors**: All trainees, junior faculty, and study staff should be acknowledged, as appropriate, in the contributors/acknowledgements section of manuscripts.

21.9.3 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 with enrolling participants will be acknowledged in the article and generally listed in order according to the number of participants enrolled. The listing may also include other participants who satisfy the Uniform Requirements, such as representatives of the SDSU, LOU, protocol specialists, DMID, EMMES, and industry or other collaborators. The listing will be compiled by the writing team chair, protocol team chair, and protocol specialist. The Publications Coordinator will confirm that there is an appropriate appendix of contributors upon submissions for CPC routing for review. The Publications Coordinator will confirm the listing with the protocol specialist, SDSU and/or LOU representative should they not be included in the listing of contributors.

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 some cases, the journal may allow a second appendix; when this is allowed, all members of the study team should be included.

In general, this policy to acknowledge contributors applies to any Conference Presentation Materials.

21.10 Acknowledgements

21.10.1 Network and NIH Acknowledgements

The IDCRC Network and the specific DMID protocol number should be included in the title and body of the manuscript (e.g., IDCRC XXXX-XXXX or DMID XX-XXXX).

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

> *"**Supported by the Infectious Diseases Clinical Research Consortium through the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, under award number UM1AI148684. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.**"*

21.10.2 Other Acknowledgements

If the work represented by the manuscript was directly supported by VTEU funding or other sponsors, they should also be acknowledged accordingly and in keeping with the terms of any applicable CTAs, MOUs, or other collaboration and sponsor agreements. For NIAID held agreements, this is a NIAID responsibility which is completed as part of their review. It is the responsibility of the writing team chair and protocol team chair to ensure appropriate acknowledgement of contributors, sponsors, and collaborators.

21.11 Public Access Policy

The IDCRC 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 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 CPC 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.

21.12 Executive Summaries and Accompanying Materials

The primary purpose of an Executive Summary is to disseminate data generated from IDCRC 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.

For Phase III studies and for certain other studies with results that could alter the standard of care for 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), PS(s), and MO(s), will prepare a draft Executive Summary based on the core analysis report. A summary is part of the DMID template for Clinical Study Reports.

The draft Executive Summary will be reviewed and agreed by the protocol team (minimally, the protocol chair(s), protocol statistician(s), Medical Officer (s), Protocol Specialist(s), and industry representatives), the IDCRC CPC, and NIAID/DMID before being distributed to participating investigators and others, and the terms of any DMID or contractual 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 Protocol Specialist will then forward the final draft Executive Summary to the CPC and DMID 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 IDCRC review process and approved by DMID. In the event of a disagreement between the reviewers and the protocol team, other members of the CPC should be consulted. If an urgent Executive Summary is required, this timeline may be altered based on the circumstances, as approved by the CPC chair and DMID.

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 CPC and DMID have reviewed 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 Medical Officers, OCRR Program Officer(s)
- IDCRC PI's, LOC Chairs, LOU and SDSU Directors
- 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.

For studies conducted under an IND held by DMID, DMID will submit the CSR to the FDA, which includes the template for an executive summary.

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 publications.

Press Releases (please refer to MOP 7.3.2)

All Network-related press releases and public statements will be developed or reviewed by NIAID, as appropriate. When such materials are developed by the sponsor(s), NIAID and IDCRC LOC will coordinate review by Network and/or study leaders as needed; reviews should take place in parallel to preserve timelines. When these materials are developed within the Network, IDCRC LOC will ensure that they are reviewed by required groups. Before any materials undergo NIH review, the IDCRC LOC ensures they have been reviewed and/or approved by relevant parties within the Network. Study- related press releases and materials must be approved by the protocol chair and the IDCRC Network chair.

21.13 Abstracts and Posters

Abstracts and poster papers reporting results of IDCRC studies or otherwise based on IDCRC study data may not be presented at a conference or other public venue without CPC review and approval. Authorship should generally follow the guidelines as included in Section 21.9, 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 NIAID/DMID, industry or other sponsors/collaborators as specified in the CTA or other third-party agreement. The writing team chair is responsible for ensuring that all applicable reviews are completed, and approvals are obtained prior to

conference submission.

The primary author must submit the draft abstract or poster to the Publications Coordinator and to NIAID/DMID no later than 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/poster should be submitted for review at the earliest possible time, and no later than three working days prior to the abstract submission deadline. If the data necessary to complete the abstract are not available within the designated timeframe, an alternate review process may be determined by mutual agreement of the writing team and the CPC chair.

An IDCRC 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 should be provided to the abstract author with a copy to the Publications Coordinator for tracking.

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.

All abstracts and posters that include IDCRC trial data must acknowledge the IDCRC (as well as the VTEU(s) as appropriate), specifying the grant number of all entities contributing to the study, as applicable. In addition, all publications must include a disclaimer such as “the content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” For abstracts, include the disclaimer in the poster or in the PowerPoint presentation.

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 CPC prior to resubmission if substantive changes are made.

Table 21-2.1 Timeline for Development and Review of Tier 1 and Tier 2 Primary Manuscripts

Event	Timeline	Procedures	Responsible Party
Formation of writing team	Primary authors identified by protocol chairs during the study. Remainder of writing team to be finalized before anticipated primary completion date or closed to follow-up date (whichever comes first)	Hold 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) • Begin compilation of the appendix of contributors	Protocol team and protocol specialist to coordinate
Primary completion date (e.g., LSLV) or closed to follow-up date (whichever comes first); final data entry period begins	Day 0	Notify Publications Coordinator	Protocol Specialist to the COU
Receipt of TFLs required for primary outcome analysis by protocol chair/writing team chair	3-4 months (up to 16 weeks) after primary completion/closed to follow-up date	Document receipt of TFLs in study milestone document	Protocol Specialist to document information provided by the SDCC
Manuscript preparation	Writing period should take approximately 8 weeks after the protocol chair's receipt of CSR/FSR v0.1 (unless writing team identifies additional analyses needed for the primary manuscript), 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	• Provide protocol chair/writing team chair with expected 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/sponsors/site PIs/pharmaceutical representatives and incorporate comments within 4 weeks.	PS or publications coordinator Protocol chair Protocol chair/writing team chair and other members Protocol chair/writing team chair and PS

Event	Timeline	Procedures	Responsible Party
Manuscript submission for IDCRC review	Within 4 weeks of CSR/FSR v1.0 All reviewers are appointed within 3 working days.	• Submit manuscript to publications coordinator indicating protocol number, primary/second manuscript, and to which journal the team will be submitting, if known. • Forward manuscript to IDCRC CPC Chair for review. • Forward to DMID for review. • Designate **one content reviewer** or request appointment of alternate. • Appoint alternate reviewer if necessary and request statistical review if needed. • Confirm appropriate appendix of contributors and inclusion of Network and NIH acknowledgements.	Writing team chair/primary author/delegate Publication's coordinator EWG Chair CPC Chair Publication's coordinator
IDCRC review	Review returned within 5-7 working days after request for review. Revision returned to reviewer (if requested) within 5-7 working days of receipt of comments.	• Reviewer (s) will forward review comments and approval (or resubmission request) to writing team chair. • Address reviewer comments • If reviewer (IDCRC or DMID) requests resubmission review, a) submit response and revised manuscript to publications coordinator/reviewer as requested. • If disapproved, submit a revised manuscript (substantial changes to be agreed upon by authors, protocol team (including pharmaceutical company representatives, if applicable), primary reviewer, and IDCRC Publications Group chair).	Reviewer Writing team. Writing team chair/primary author/delegate
IDCRC-approved primary manuscript submitted to journal	Within 4 weeks of IDCRC and DMID approval	• The CPC Chair or any reviewer may request an additional review by a member of the Leadership Operations Center (LOC) • Submit manuscript to journal and send copy to publications coordinator. • Ensure authors' disclosure of potential conflicts of interest as required by journal policy. • See Section 21.8 for additional guidance related to journal submission and procedures for various outcomes	Writing team chair/primary author Writing team

Event	Timeline	Procedures	Responsible Party
Acceptance for publication	Following journal submission	• Communicate outcome of submission to publications coordinator • 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 publication's coordinator. - submit manuscript to PubMed Central via the NIHMS on behalf of the corresponding author and supply the author with a NIHMS ID - approve the release and PubMed Central formatting of manuscript upon receipt of the email notification from NIHMS	Writing team chair

Table 21-2.2 Timeline for Development and Review of Secondary Manuscripts

Event	Timeline	Procedures	Responsible Party
Formation of writing team	Primary authors can be identified by the protocol team at any time up to 6 months after primary completion date or closed-to-follow-up date (whichever comes first).	Hold team call(s) to include discussion of writing team formation and agree on communications plan	Protocol chair, protocol team including Protocol Statistician
Manuscript preparation begins; 3-month (14-week clock starts)	Writing period should take no more than 8 weeks after the writing team's receipt of the analysis report, leaving at least 4 weeks for authors, writing team, protocol team, others(including NIH, pharmaceutical company representatives, etc.) and incorporation of comments/ revisions	• Determine number and order of masthead authors. • Develop full manuscript within 8 weeks. • Distribute for review by team/authors/sponsors/site PIs/pharmaceutical representatives and incorporate comments within 4 weeks. • Begin compilation of the appendix of Contributors	Protocol chair/writing team chair and other members Writing Team Writing Team Chair
Secondary Manuscript submission for IDCRC review	Recommended: no more than 3 months after publication of primary manuscripts for secondary manuscripts. All reviewers appointed within 3 working days.	• Submit manuscript to publications coordinator indicating protocol number, primary/second manuscript, and to which journal the team will be submitting, if known. • Forward manuscript to IDCRC CPC Chair for review. • Forward to DMID for review. • Request EWG Chair to designate **two content reviewers** or request appointment of alternates. • Appoint alternate reviewers if necessary and request statistical review if needed. • Confirm appropriate appendix of contributors and inclusion of Network and NIH acknowledgements.	Writing team chair/primary author/delegate Publication's coordinator EWG Chair CPC Chair Publication's coordinator

Event	Timeline	Procedures	Responsible Party
IDCRC review	Review returned within 5 - 7 working days after request for review. Revision returned to reviewer within 5-7 working days of receipt of comments.	• Reviewers will forward review comments and approval (or resubmission request) to writing team chair/primary author, with copy to Publications Coordinator • Address reviewer comments • If reviewer (IDCRC or DMID) suggests revisions: a) Submit response and revised manuscript to publications coordinator/reviewer. b) If disapproved, submit a revised manuscript (substantial changes to be agreed upon by authors, protocol team (including pharmaceutical company representatives, if applicable), primary reviewer, and IDCRC Publications Group chair. • The CPC Chair or any reviewer may request an additional review by a member of the Leadership Operations Center (LOC)	Reviewer Writing team Writing team chair/primary author/delegate
IDCRC-approved secondary manuscript submitted to journal		• Submit manuscript to journal and send copy to Publications Coordinator • Ensure authors' disclosure of potential conflicts of interest as required by journal policy. • See Section 21.8 for additional guidance related to journal submission and procedures for various outcomes	Writing team chair/primary author

REVISION HISTORY:

Version number	Approval Date DD MMM YYYY	Summary of Changes
4.0	22 MAR 2024	Modified guidance for writing team members in section 21.2.7. Added confirmation step for appendix of contributors, section 21.9.3. Made corrections to various section references.
5.0	14 Jan 2026 20 May 2026	Adjusted timeline guidance to base on CSR/FSR v1.0 Original final version posted to IDCRC website was not the same in content as approved by EMT. Corrections made to Table 21-2.1 Timeline for Development and Review of Tier 1 and Tier 2 Primary Manuscripts to align with CSR/FSR v1.0 not TFLs.