Antibacterial Resistance Leadership Group (ARLG) Publication Policy

I. Introduction:

The ARLG Publication Policy directs the review and approval of all publications, presentations, and meeting abstracts intended to represent ARLG-supported studies.

II. Purpose:

This Policy documents the role and membership of the ARLG Publications Committee, the process of review, and the requirements for approval pertaining to publications and presentations intended to represent ARLG.

III. Scope:

This Policy applies to all individuals involved in developing publications derived from work supported in total or in part by ARLG funds, using ARLG strains, or intended to represent the ARLG.

IV. Definitions:

<table>
<thead>
<tr>
<th>Affiliated Studies</th>
<th>Studies that utilize some assay results or data generated as part of an ARLG study, or require analysis time from an ARLG statistician or scientific input from an ARLG-funded individual or transient/limited funding (but the majority of the effort and data were funded using alternate sources). Examples include ESI Seed Grants, transient studies (studies whereby support may supplement funding until closure), and diagnostics or industry studies that utilize intellectual property or resources from ARLG</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARLG</td>
<td>Antibacterial Resistance Leadership Group</td>
</tr>
<tr>
<td>ARLG Strains</td>
<td>Strains provided to investigators through the ARLG Laboratory Center</td>
</tr>
<tr>
<td>ARLG Studies</td>
<td>Studies that are approved by the ARLG Executive Committee, and which receive significant contributions or support in design and/or execution and analysis (either monetarily or with resources from the Laboratory Center, Statistics and Data Management Center, Clinical Operations Center or by ARLG faculty consultation)</td>
</tr>
<tr>
<td>COC</td>
<td>Clinical Operations Center</td>
</tr>
<tr>
<td>CPM</td>
<td>Clinical Project Manager</td>
</tr>
<tr>
<td>DMID</td>
<td>Division of Microbiology and Infectious Diseases, NIAID, NIH</td>
</tr>
<tr>
<td>ESI</td>
<td>Early Stage Investigator</td>
</tr>
<tr>
<td>ICMJE</td>
<td>International Committee of Medical Journal Editors</td>
</tr>
<tr>
<td>NIAID</td>
<td>The National Institute of Allergy and Infectious Diseases</td>
</tr>
<tr>
<td>NIH</td>
<td>The National Institutes of Health</td>
</tr>
<tr>
<td>Primary Manuscripts/Abstracts</td>
<td>Manuscripts or abstracts that report data and results of the primary objectives of an ARLG study</td>
</tr>
<tr>
<td>Secondary Manuscripts/Abstracts</td>
<td>Manuscripts or abstracts that report secondary analysis results or objectives of an ARLG study, or scientific questions outside of the primary objectives (e.g., baseline</td>
</tr>
</tbody>
</table>
V. Policy:

All manuscripts, abstracts, presentations at scientific meetings (in format of slides or posters), and any other publications including web-only articles, and electronic transmissions to any public domain, derived from work supported in total or in part by ARLG funds, using ARLG strains, datasets, or specimens, or intended to represent the ARLG (i.e., “publications”) must, before submission to a scientific journal, conference, organization, or other publishing body, or before being posted in a public domain, be submitted to the ARLG Publications Committee and routed for ARLG review as detailed below.

A. Role and Membership of the ARLG Publications Committee

It is the policy of the Publications Committee that appropriate acknowledgement of ARLG contributions are cited and, in certain circumstances, that the study results are presented by individuals who have working knowledge of the study design, implementation, data synthesis/analysis, and interpretation as intended. The goals of the Publications Committee are to ensure that any confidential or proprietary information is protected, and that appropriate statistical analyses were executed.

The Publications Committee serves to approve the Publication Policy (subject to ARLG Executive Committee final approval); define the purpose of ARLG review, what has to be reviewed, and the review process; resolve conflict if it occurs among the authors (see Section B.2.1); and decide on the final disposition for publications not meeting acceptable review criteria [as determined by the reviewer(s)]. In addition, the Publications Committee can develop strategies for additional studies and ongoing research, and review proposed topics for methods papers, review papers, and opinion articles from ARLG members.

The Publications Committee Chair appoints the reviewers and brings issues or policy concerns to the Committee as needed.

The Publications Committee consists of all the members of the ARLG Steering Committee (SC). The Chair and Vice-Chair of the ARLG SC serve as the Chair and Vice-Chair of ARLG Publications Committee. The Publications Committee consists of:

- ARLG Co-Principal Investigators
- ARLG Statistics and Data Management Center Director and Associate Director
- ARLG COC Director and Associate Directors
- ARLG Mentoring Committee Chair
- ARLG Laboratory Center Director and Associate Director
- ARLG Scientific Leadership Center Directors and Associate Directors
- Chairs of the ARLG Scientific Subcommittees:
  - Gram Positive
  - Gram Negative
The Publications Committee Manager is Erin Campbell (919-668-8982; erin.campbell@duke.edu).

The Publications Committee will meet face-to-face annually, and ad hoc as needed. During these meetings, the committee will review and revise the Policy as needed, review the ARLG publications reports, and develop strategies for additional studies and publications from ARLG members.

The Publications Committee shall continue until the end of the grant. Should the Publications Committee disband, all publications thereafter shall be submitted to the ARLG Co-Principal Investigators for review and comment.

B. Publications

1. Requirements

All publications must conform to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (International Committee of Medical Journal Editors [ICMJE]) with regards to authorship, disclosure, scientific integrity, and other requirements. All public presentations shall be consistent with usual academic standards. As a reminder, all applicable clinical trials must be registered in ClinicalTrials.gov prior to enrollment of the first subject.

2. Authorship

All authors listed should have contributed significantly to the design and development, statistical design or analysis, laboratory methodology, or any other significant operational or scientific aspect of the study per ICMJE guidelines.
These may include the following:

- Protocol Principal Investigator
- Lead statistician performing the analysis
- Clinical site investigators with significant contributions of samples, data, or enrolled patients
- Other authors who meet the authorship criteria of peer-reviewed scientific journals
- For primary and secondary manuscripts from ARLG studies (see Section IV Definitions), “The Antibacterial Resistance Leadership Group” must be listed after the last author. If required by the journal publisher, the authors may provide a list of ARLG members by name for the Acknowledgment section. This list, which is not exhaustive, may include, for ex. the ARLG SC members, or members of the operations team and other significant contributors, if they are not co-authors. The authors must request the current list of ARLG SC by name from the Publications Manager.

2.1. Conflict Resolution

Disagreements or other conflicts about first, second, senior or other authorship of the publication or presentation of results derived from work supported in total or in part by ARLG funds, or intended to represent the ARLG, will be resolved by the ARLG Publications Committee whose decision will be final. Members in conflict with study authors will recuse themselves from the committee review process. In case of a tie the Publications Committee Chair will hold the tie-breaking vote.

3. Funding Acknowledgements

The following must be stated to acknowledge funding for ARLG studies (see Section IV Definitions):

“Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number UM1AI104681. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

For publications arising from affiliated studies (see Section IV Definitions), the acknowledgement should be modified to state the following:

“Research reported in this publication was supported in part by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number UM1AI104681. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”
3.1. Publications Authored by ARLG Fellows

ARLG Fellows should acknowledge financial support from ARLG in all publications during their fellowship and not only in those directly related to ARLG or affiliated studies, and they should submit these publications to the ARLG Publications Committee (see Table 1 for details). Manuscripts reporting results of studies or work not supported by ARLG for which the Fellow is an author or co-author will be evaluated by the Publications Committee Manager for compliance with the statement of acknowledgement, but will not be reviewed.

The following statement of acknowledgment must be included in all publications by ARLG Fellows:

“[Fellow’s name/initials] was supported by an Antibacterial Resistance Leadership Group fellowship [National Institute of Allergy and Infectious Diseases UM1AI104681]. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

If the ARLG Fellowship provides only partial support, the following must be stated:

“[Fellow’s name/initials] was supported in part by an Antibacterial Resistance Leadership Group fellowship [National Institute of Allergy and Infectious Diseases UM1AI104681]. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

3.2. Publications Authored by Early Stage Investigator (ESI) Seed Grant Recipients

Seed Grant recipients should acknowledge financial support from the ARLG only in publications derived from ARLG-funded studies, and they should submit these publications to the ARLG Publications Committee for review (see Table 1 for details).

The following statement of acknowledgment must be included in publications by ESIs:

“Research reported in this publication was supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health under Award Number UM1AI104681. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”
3.3. Reference of ARLG Bacterial Strains

ARLG strains (see Section IV Definitions) must be referenced by their ARLG-assigned ID number in all publications.

The recipient scientist should provide appropriate acknowledgment in all publications and presentations by use of the following language:

“Bacterial isolates identified as “ARLG” were provided by the Antibacterial Resistance Leadership Group Laboratory Center, which is supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number UM1AI104681. Findings, opinions, and recommendations expressed herein are those of the authors and not necessarily those of the National Institutes of Health.”

For ARLG studies that report results on clinical isolates that will be deposited to the ARLG Biorepository, after the appropriate funding acknowledgment (see Section B.3 Funding Acknowledgments), the following statement should be included:

“Bacterial isolates reported in this study may be available, subject to approval, through a request to the Antibacterial Resistance Leadership Group Laboratory Center, which is supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number UM1AI104681.”

C. Presentations

The study principal investigator or other team member presenting data as an oral or poster presentation from ARLG studies at scientific meetings must use the ARLG logo and acknowledge the grant using the appropriate acknowledgement statement. The ARLG logo, template slides, and template poster are available upon request to Publications Committee Manager.

D. Submissions

All submissions to the ARLG Publications Committee, at any stage of review, are to be made through the ARLG Publications Committee Manager. Manuscripts and abstracts will be submitted via email in an editable electronic format, such as Microsoft Word. The author is notified of receipt by e-mail.

The Publications Committee Manager will review all submissions for proper citation of ARLG contributions. For submissions involving ARLG studies, affiliated studies, studies funded through an ARLG Fellowship or ESI Award (Seed Grant), the publication will be further routed to the ARLG Publication Committee Chair for review assignment. All submitted publications will be tracked. Authors must report the final disposition (e.g.,
acceptance, rejection, resubmission to an alternate journal, etc.) of publications to the Publications Committee Manager.

At the time of submission to the ARLG Publications Committee, particularly for manuscripts reporting results of affiliated studies, secondary manuscripts or abstracts, or studies for which principal funding is provided by an entity other than the ARLG, the submitter must indicate whether a conflict of interest exists with any of the members of the Publications Committee, or potential alternate reviewers. The Publications Committee Manager will ensure that the publication is not circulated to the conflicted member.

Publications for studies only using ARLG strains should be submitted to Dr. Carol Bova Hill (919-668-8064; carol.hill@duke.edu) for review to ensure compliance with the acknowledgment and Material Transfer Agreement requirements.

E. Review Process

Upon submission, the Chair of the Publications Committee shall assign at least two reviewers for each manuscript and at least one reviewer for each abstract, poster or slide presentation, or other publication that qualifies for ARLG review. Reviewers will be selected from among ARLG committee members according to their expertise. Each assigned reviewer has the right to delegate review to a designee with an appropriate level of expertise.

The purpose of the ARLG review is to assure that the manuscript is accurate and appropriate in its methods and reporting, and interpretation of results, and that the appropriate acknowledgment has been cited. Reviewer(s) will review the author line with the standard criteria for scientific authorship in mind, determine whether conflicts of interest exist, and assess the balance and accuracy of data presentation and results. The reviewer(s) shall consider each publication with due regard for the scientific merit of the proposed publication with the aim of promoting the timely dissemination of scientific and medical knowledge. Reviewers may, but are not required to do so, function as though they were a peer reviewer for a journal and provide additional comments wordsmithing, etc., to aid the authors, but this is not the main responsibility (see Section X Appendix).

The Publications Committee Manager will facilitate correspondence between reviewers and the primary author(s) of each publication. (Otherwise, the Publications Committee Manager should be copied on all correspondence between the reviewers and the primary author[s].)

Publications not meeting acceptable review criteria will be referred to the Publications Committee for final determination of suitability for publication. In the situation that the Publications Committee does not endorse a proposed manuscript or presentation, the author still maintains the right to present locally collected, generated, or analyzed data. However, the author may not include aggregate ARLG study results without Publications Committee approval and must include the following disclaimer:

“This [publication type] is not endorsed by the ARLG Publications Committee.”
Time allowed for review is 10 working days for manuscripts. Abstracts must be submitted at least 5 working days prior to the abstract submission deadline and presentation date (see Table 1 for details).

Only those review comments received on time will be considered. The review time begins when the draft publication is sent to reviewer(s) by the ARLG Publications Committee Manager.

**Table 1. Timelines for ARLG Publications Review**

<table>
<thead>
<tr>
<th>Publication Type</th>
<th>Submission to ARLG</th>
<th>ARLG to NIAID/DMID</th>
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<tbody>
<tr>
<td>Manuscripts from ARLG or affiliated studies</td>
<td>10 working days prior to submission</td>
<td>N/A (NIAID/DMID included in Publications Committee)</td>
</tr>
<tr>
<td>Abstracts from ARLG or affiliated studies</td>
<td>5 working days prior to submission</td>
<td>N/A (NIAID/DMID included in Publications Committee)</td>
</tr>
<tr>
<td>Presentations (slides and posters) from abstracts from ARLG or affiliated studies</td>
<td>At least 10 working days prior to presentation</td>
<td>N/A</td>
</tr>
<tr>
<td>Publications from ARLG Fellows as author or co-author not involving ARLG or affiliated studies</td>
<td>5 working days prior to submission</td>
<td>N/A</td>
</tr>
<tr>
<td>Publications Committee Manager will review for compliance with the acknowledgment statement. These will be not be reviewed.</td>
<td></td>
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</tr>
<tr>
<td>Studies using ARLG strains</td>
<td>As detailed in the Material Transfer Agreement. These publications will be routed to Dr. Carol Bova Hill for review (see Section D).</td>
<td>N/A</td>
</tr>
<tr>
<td>Press releases</td>
<td>5 working days, or per contractual agreement</td>
<td>NIAID/DMID Program Officer, CPM to review</td>
</tr>
</tbody>
</table>
F. Publicity and Media

Media inquiries and press releases must be first reviewed by the Protocol PI involved (as applicable), or other ARLG representative, the Protocol PL, anyone quoted in the release, and then referred to the NIAID/DMID Program Officer and the NIAID/DMID CPM. The NIAID/DMID Program Officer or CPM will ensure NIAID/DMID review. The Protocol PL will ensure Duke University review by the Director, Marketing Communications, Sarah Avery (sarah.avery@duke.edu) and the VP News, Comm Svcs & MKTG, Rob Odom (rob.odom@duke.edu), or designees. If these contacts are no longer available, the Protocol PL should consult with DCRI communications. Local media activity should be coordinated with the NIAID/DMID (see Table 1 for details). Protocol PLs will consult relevant contractual agreements and follow additional applicable requirements.

G. Review by Industry Partners Prior to Publication

It is the responsibility of the Protocol PI to ensure that contractual terms on the review of publications (manuscript, abstract or presentation) by industry partner(s) involved in the research project are followed and that the industry partner(s) have had the opportunity to review before publication.

H. Fundamental Errors in Published Works

Should an author discover a significant error or inaccuracy in a published work from an ARLG or affiliated study, the author should promptly notify the ARLG Publications Committee Manager.

I. NIH Public Access Policy Compliance

All authors must follow the National Institutes of Health (NIH) Public Access Policy. For questions regarding the policy, please see the NIH Public Access Policy Frequently Asked Questions.

The Publications Committee Manager will ensure that all published manuscripts are submitted to PubMed Central, as required. (For a list of journals that automatically submit articles to PubMed Central, please visit https://publicaccess.nih.gov/submit_process_journals.htm.)

As part of the NIH policy, authors are responsible for:

a) Copyright compliance - Authors must ensure that agreements with publishers permit the submission of the author’s manuscript to NIH. Upon submitting your manuscript to the journal, please alert the publisher to the fact that the manuscript is subject to NIH policy.

b) Citing PubMed Central ID numbers - When a manuscript is submitted to the NIH, the publication will receive an NIH Manuscript Submission (NIHMS) ID number. Once a manuscript is available in PubMed Central, it will be assigned a PubMed Central ID number. Effective May 25, 2008, authors must cite PubMed Central ID or (NIHMS ID) numbers for any articles cited in progress reports, new applications, and renewals.
VI. References:

1. Instructions for submissions to ClinicalTrials.gov at: https://clinicaltrials.gov/
5. List of journals that automatically submit articles to PubMed Central at https://publicaccess.nih.gov/submit_process_journals.htm

VII. History of Change:

<table>
<thead>
<tr>
<th>Section Affected</th>
<th>Changes Made v2.0 to v3.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>V. A. Role and Membership of the ARGL Publications Committee</td>
<td>Added Diversity WG Chair</td>
</tr>
</tbody>
</table>
| V. B. 3.3 Reference of ARLG Bacterial Strains          | Revised acknowledgment for studies that used isolates provided by the ARLG Laboratory Center
                                                      | Added statement for ARLG studies that report results on clinical isolates that will be deposited to the ARLG Biorepository                                |
| V. F. Publicity and Media                             | Added the Duke University Director of Marketing Communications and the VP News, Comm Svcs & MKTG                                                                 |
| V. G. Review by Industry Partners Prior to Publication | Section revised to indicate the responsibility of the Protocol PI to ensure that industry partners had the opportunity to review and that contractual terms related to review by industry partners are followed. |
Signatories

<table>
<thead>
<tr>
<th>Lead Author (Name, Role)</th>
<th>Signature and Date</th>
</tr>
</thead>
</table>
| Maria Souli, M.D.        | Electronically signed by: Maria Souli  
Reason: Authored this document.  
Date: Apr 9, 2021 17:12 EDT |
| Project Leader          | Maria Souli         |

<table>
<thead>
<tr>
<th>Authorizer (Name, Role)</th>
<th>Signature and Date</th>
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</thead>
</table>
| Heather Cross, DPhil     | Electronically signed by: Heather R Cross  
Reason: Authorized Document  
Date: Apr 9, 2021 17:24 EDT |
| ARLG COC Director        | Heather R Cross     |
VIII. Appendix

Instructions for Reviewers of ARLG Publications, Presentations, and Meeting Abstracts Intended to Represent ARLG-Supported Studies

- Provide your review or communicate any issues or concerns to Publications Committee Manager, Erin Campbell (919-668-8982; erin.campbell@duke.edu)
- You should recuse yourself and notify the Publications Committee Manager if you identify a conflict
- Provide your review in accordance with timeline indicated below:

<table>
<thead>
<tr>
<th>Type of publication</th>
<th>Timeline for review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manuscript</td>
<td>10 working days</td>
</tr>
<tr>
<td>Abstract</td>
<td>5 working days</td>
</tr>
<tr>
<td>Slide and Poster presentations</td>
<td>10 working days</td>
</tr>
</tbody>
</table>

- You may delegate the review to a designee with an appropriate level of expertise
- The purpose of the ARLG review is to assure that the manuscript is accurate and appropriate in its methods, and reporting and interpretation of results, not whether it should be accepted or rejected for publication by a journal
- It is not your main responsibility, and you are not required to do so, but you may provide additional comments, wordsmithing, etc., to aid the authors
- Checklist for your review process:
  - Is the appropriate statement for acknowledgment cited?

For ARLG studies:

"Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number UM1AI104681. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

For affiliated studies:

"Research reported in this publication was supported in part by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number UM1AI104681. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

For studies authored by Fellows:

“[Fellow’s name/initials] was supported by an Antibacterial Resistance Leadership Group fellowship [National Institute of Allergy and Infectious Diseases UM1AI104681]. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

For studies authored by Fellows who received only partial support by ARLG:

“[Fellow’s name/initials] was supported in part by an Antibacterial Resistance Leadership Group fellowship [National Institute of Allergy and Infectious Diseases UM1AI104681]. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

☐ Does the author line comply with the standard criteria for scientific authorship (ICMJE guidelines)?

☐ For a primary or secondary manuscript from an ARLG study, is “The Antibacterial Resistance Leadership Group” listed after the last author?

☐ Is there a conflict of interest not appropriately disclosed?

☐ Assess the balance and accuracy of data presentation and results, and their overall scientific integrity

☐ Consider the scientific merit of the proposed publication with the aim of promoting the timely dissemination of scientific and medical knowledge
"ARLG-P001_Publi cation Policy_08APR2021_v3.0_FINAL" History

Document created by Maria Souli (ms708@duke.edu)
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Document e-signed by Maria Souli (ms708@duke.edu)
Signature Date: 2021-04-09 - 9:24:13 PM GMT - Time Source: server - IP address: 152.16.191.131

Agreement completed.
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