

***RADx-UP Publications Policy***

For Consortial Research Products

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## I. Introduction

Under the direction of the RADx-UP Publications & Dissemination Committee, the Publications Policy directs the development and review of scholarly products (abstracts, scientific presentations, manuscripts) derived from information and data from RADx-UP aggregated within the Coordinating and Data Collection Center (CDCC).

## II. Purpose

The overarching goals of the RADx-UP Publications Policy are to:

- Effectively and efficiently employ RADx-UP data to advance understanding and knowledge about the program and projects.
- Encourage timely development of high-quality RADx-UP data analyses, abstracts, presentations, and manuscripts.
- Promote innovation in COVID-19 research and findings in underserved populations.
- Maximize impact of research through dissemination.
- Encourage equity, reproducibility, and transparency in the development of RADx-UP research and research products.
- Support a process that encourages collaboration.

## III. Scope

This policy applies to all individuals involved with writing or reviewing abstracts, presentations, and manuscripts derived from RADx-UP data aggregated within the CDCC that are supported by RADx-UP funds or represent RADx-UP (i.e., consortial publication products).

*(Individuals involved with writing nonconsortial research products derived from RADx-UP data from their individual project should refer to the publication stipulations of their individual NIH award. ALL authors should inform the CDCC [Abisola Osinuga; abisola\_osinuga@med.unc.edu] about their RADx-UP publications, and all presentations and publications emerging from grant-supported activities of RADx-UP must acknowledge NIH support, as detailed below.)*

The NIH RADx-UP Program recognizes all laws and regulations concerning Tribal Sovereignty for American Indian and Alaska Natives. All specifications in Tribal Nations Publications Agreements that deviate from the contents of this policy will supersede the requirements laid out in this policy. The RADx-UP CDCC Publications & Dissemination Committee will review, revise, and approve this Publications Policy on a regular basis.

Consortial research products produced by RADx-UP awardees are expected to adhere to the following sections of the Publications Policy:

- Use of the RADx-UP logo in presentations (Section V, Part E);
- Acknowledgment of National Institutes of Health support (Section V, Part D);
- Submission to the CDCC Publications Group (RADx-UP-Publications@duke.edu) for tracking and reporting purposes (Section V, Part B, Subsection 1) and review by the RADx-UP Publications & Dissemination Committee;
- PubMed Central submission of manuscripts (Section V, Part F).

## IV. Definitions

Term	Explanation
<b>Analysis Concept</b>	A preliminary, informal submission of interest in using aggregated data from the RADx-UP Data Platform to answer a specific scientific question. This brief form will be shared with the rest of the RADx-UP consortium to provide members and project teams the opportunity to review submitted concepts, suggest refinements, and request inclusion (as active participants) in the writing teams.
<b>Analysis Proposal</b>	A formal request submitted by an investigator to use data from the RADx-UP Data Platform to answer a scientific question. The investigator (lead author) will complete an <i>Analysis Proposal</i> via <a href="#">myRADx-UPhome</a> that will include information such as research question, background and motivation, aims/hypotheses, conceptual model, study population, measures, statistical approach, and intended journal. The analysis proposal will be reviewed and considered for approval by the RADx-UP Publications & Dissemination Committee (see review criteria below and in Publications & Dissemination Committee Charter). Approved analysis proposals will be posted for the RADx-UP Consortium’s review and logged to track data use and prevent duplicate analyses. Once the proposal has been approved, analyses can begin; when completed, the lead author and co-authors write a manuscript (and abstract) to summarize and share their findings. Investigators whose proposal is rejected are encouraged to consider the committee’s comments and rationale for rejection, and incorporate these comments into a new proposal if applicable.
<b>Consortial Publication</b>	A product derived from RADx-UP data aggregated within the CDCC that is supported by RADx-UP funds or represents RADx-UP.
<b>Nonconsortial Publication</b>	A product derived from data collected by a RADx-UP project that is supported by RADx-UP funds or represents RADx-UP but is not derived from aggregated RADx-UP data.
<b>Publications &amp; Dissemination Committee</b>	The governing body that upholds the RADx-UP Publications Policy.

## V. Policy

### A. Publications & Dissemination Committee

The RADx-UP Publications & Dissemination Committee is responsible for reviewing analysis proposals and research products (abstracts, presentations, and manuscripts), and maintaining and upholding the RADx-UP Publications Policy, including COVID-19 focus and recognition and adherence to the preferences and requirements of the communities served by RADx-UP.

The committee’s proposal review criteria include the following:

- Is the proposal in line with the RADx-UP mission?
- Are the hypotheses and specific aims appropriate for a single paper rather than multiple papers?
- Are the hypotheses appropriate and clearly articulated?
- Are the specific aims clearly articulated and consistent with the hypotheses?
- Does this proposal avoid overlap with existing Analysis Proposals?
- Is the proposal feasible?
- Are the proposed statistical methods well-articulated and generally appropriate?
- Are community partners involved as appropriate in the design or conception?
- Does the proposed research avoid doing harm to the community being studied?

All RADx-UP research products submitted for publication in the peer-reviewed literature will follow the International Committee of Medical Journal Editors' (ICMJE) *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*.

Detailed information on the role of the Publications & Dissemination Committee can be found in the Publications & Dissemination Committee Charter.

The RADx-UP Publications & Dissemination Committee scope of work *may* include providing input into prioritizing analysis proposals.

## **B. Authorship: Lead Author**

### **1. Lead Author**

The lead author may recruit co-authors (academic and/or community partner co-authors from within or outside the RADx-UP program [see Part C below for more guidance on this]) to assist with the development of the analysis concept or the analysis proposal, and to co-author resulting research products (i.e., abstract, presentation, manuscript).

The lead author will be the primary contact with the CDCC and Publications & Dissemination Committee. The lead author is usually the first author listed.

Throughout the process, the lead author should keep in mind the importance of collaboration and inclusiveness (see Appendix A).

*The lead author's responsibilities include:*

- Initiating an analysis concept and submitting via [myRADx-UPhome](#). Adding writing team members as appropriate to assist with the development of the analysis proposal and subsequent research products.
- Submitting the analysis proposal via [myRADx-UPhome](#).
- Responding to Publications & Dissemination Committee review of the analysis proposal (see Publications & Dissemination Committee Charter). The possible outcomes of review at this stage are (1) approval for analyses to proceed; (2) approval for analyses to proceed, with recommended changes; (3) revisions and resubmission of the proposal required; or (4) rejection – analyses may not proceed.

- Promptly developing an abstract once the data analysis results are available, for submission to an appropriate meeting (unless no abstract is planned). This includes finalizing the list of authors for the abstract. If the meeting limits the number of authors, the lead author will decide (with input from co-authors) which authors they will list.
- Promptly drafting a manuscript (typically within 8 weeks of receiving data analysis results). This includes finalizing the list of authors for the manuscript (this list may include additional authors to those in the meeting abstract). If the target journal chosen by the writing team limits the number of authors allowed for submissions, the writing team leader will decide (with input from writing team members) which authors they will list.
- Circulating a draft among co-authors and involved community partners for comments and approval (and informing the CDCC Publications Group), and sending a revised draft to the CDCC Publications Group, which will, if appropriate, initiate and coordinate review by the Publications & Dissemination Committee.
- Ensuring authors meet the ICMJE's criteria for authorship (see Part C below). The lead author should be prepared if necessary to work closely with any community partner co-authors who might need guidance on their contributions to the manuscript.
- Sending the final draft of the manuscript to the CDCC Publications Group. The CDCC medical editor may edit, format for target journal, and submit the manuscript, if requested by the lead author (or corresponding author; see Part C, Subsection 3 below).
- Notifying the CDCC Publications Group of changes of manuscript status (e.g., rejected, accepted, revisions requested, published).
- Ensuring the submission of accepted manuscripts to PubMed Central to satisfy the National Institutes of Health Public Access Policy (see Part F below).
- Produce a lay-audience-friendly description of the manuscript and findings and submit for release on the RADx-UP.org publications page.

## 2. Writing Team Appeals Process

In any large multicenter, multidisciplinary effort, conflicts are bound to arise, particularly regarding publication. Investigators should attempt to resolve conflicts by first discussing with the appropriate RADx-UP Committee or Working Group. If a conflict is not resolved by discussing with the appropriate RADx-UP entity, the investigator may formally appeal to the Publications & Dissemination Committee. The CDCC will facilitate a review of all relevant materials and provide the opportunity for the investigator to make a written or oral presentation to the Publications & Dissemination Committee, if the Publications & Dissemination Committee requests such a presentation.

## C. Authorship Guidelines

### 1. Process to Identify Authors

Before and during the development of an analysis proposal, the lead author will recruit co-authors and should consider inclusion of other RADx-UP investigators or RADx-UP community collaborators with interest and relevant expertise/experience (see below). At the time of analysis proposal submission, the lead author should include a preliminary list of co-authors. The lead author may add co-authors after review of the proposal by the Publications & Dissemination Committee. To encourage collaboration, consortium members may volunteer to participate in a joint publication.

## 2. Who Should Be Included as an Author on a RADx-UP Publication?

Authorship for RADx-UP publications will follow the ICMJE's Criteria for Authorship, which recommend authorship based on the following 4 criteria:

- a. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- b. Drafting the work or revising it critically for important intellectual content; AND
- c. Final approval of the version to be published; AND
- d. 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.

Author order (except for first and senior) is determined in accordance with the level of contribution to the writing and analysis.

### Inclusion of Community Partners as Co-authors

At the paper's inception, the lead author should communicate with any community partners involved to determine whether any staff wish to be part of the authorship team, and to ensure inclusion of those staff members who have identified a particular interest in the topic. For research questions specific to a minoritized community (i.e., based on race/ethnicity, sexual orientation, or gender identity), if the lead author is not a member of the specific community, they should include at least one representative from the community as a co-author.

*Community partners are individuals who:*

- typically represent or have strong ties to the community being engaged; or
- have direct relationships with and serve the target population at the community level; or
- have relevant lived experience whether or not they are a current member of the community being represented.\*

The community partner must meet at least one of the three conditions above, all of the ICMJE criteria listed above, and

- should contribute meaningfully to the development of the research question, analysis, interpretation, and paper as key thought partners, not tokens of diversity. For example, contributing to the conception of the work or the interpretation of data, assisting with literature review for the manuscript draft or reviewing and offering comments, providing approval of the manuscript draft, *and* agreeing to share accountability for the work would qualify a community partner as co-author per ICMJE criteria.

*\*If research involves a tribal nation, then a representative or tribal member will need to be included in the writing team.*

*Preferably, the following individuals should not be considered to fill the required role of Community Partner for consortial publications writing teams (but they can still be a co-author):*

- Academic community-engaged researchers, such as someone whose *main* occupation is as faculty or staff with a university or institute of higher learning and who is involved with a community-based organization or whose research interests include the organization, its members, or their cause.

The intent of this definition is to have at least one member of the community involved on the paper who is not well-versed in research and publications (i.e., a non-academician). If a writing team wishes to include as their community partner an individual whose primary occupation *is* with a university or institute of higher learning, they are requested to provide a justification on their analysis proposal.

If an authorship team is unable to identify a co-author with relevant lived experience and expertise, they may contact the Publications & Dissemination Committee for support or visit <https://myhome.radx-up.org/cdcc-resources/what-we-do/> for available resources, such as the consultation service delivered by Community Campus Partnerships for Health (CCPH) to support the community engagement needs of the RADx-UP projects.

Guidelines for acknowledging non-author contributors are included in the ICMJE Recommendations.

### **3. Who Should Be the Corresponding Author?**

The corresponding author should be the author (usually the lead or senior author) who is very familiar with the analysis, prepared to be responsible for communication with the journal during manuscript submission and review, and plans to be at his/her current institution for at least 1 year.

### **4. Disputes in Authorship**

Author groups should first discuss among themselves, and attempt to resolve, any disagreements about authorship. If disputes still exist, the Coordinating Center should arrange for a conference call with the RADx-UP Publications & Dissemination Committee chair(s) and the writing team member(s) to discuss and resolve the dispute. If this is not successful, the Coordinating Center should arrange a conference call with the Publications & Dissemination Committee chair(s), writing team member(s), and Executive Committee chair to discuss the dispute and develop a plan for resolution. A writing team member may also confidentially discuss a dispute about authorship decisions with the Publications & Dissemination Committee chair(s).

### **5. Technical Guidance**

- a. Sexual and gender minority populations should not be collapsed into a single category. For instance, it would be inappropriate to design an analysis that simplified outcomes to “sexual minority vs. heterosexual” unless 1) statistical tests were done that showed there were no differences among sexual/gender minority subpopulations, or 2) it would be impossible to perform the analyses with subpopulations separated due to issues of statistical power.
- b. Theoretical models must be used to explain health disparities. Papers cannot implicate any essentialist view of disparities. Health disparities are not due to inherent deficiencies of marginalized groups (i.e., race is not the cause of health disparities, racism is).
- c. Similarly, sex, race, and ethnicity are not to be treated as “biological variables.” Sex, race, and ethnicity are socially constructed categories. Authors are expected to engage with these variables as such. We recognize that sex is considered a biological variable by NIH, which

complicates this categorization. For further guidance on race and ethnicity, see the *JAMA* 2021 “Updated Guidance on the Reporting of Race and Ethnicity in Medical and Science Journals” at <https://jamanetwork.com/journals/jama/fullarticle/2783090>.

- d. We advise use of the singular “youth” rather than the pluralized “youths.”
- e. We advise against the use of othering language when discussing findings about marginalized groups, specifically avoiding saying “they/them”—i.e., say, “This population uses alcohol at higher rates” instead of “They use alcohol at higher rates.”

## 6. Presentations of Previously Published RADx-UP Data

Publications & Dissemination Committee approval is required for public presentation of RADx-UP previously presented and/or published data (i.e., presentations of previously presented/published RADx-UP data by RADx-UP investigators at local, regional, national, or international meetings). Investigators should inform and provide to the Coordinating Center Publications Group all RADx-UP-related presentations.

## D. Acknowledgment of National Institutes of Health Support

For presentations and publications emerging from grant-supported activities of RADx-UP, investigators are legally required to acknowledge funding from the National Institutes of Health, along with the following disclaimer:

**Funding acknowledgment:** *Research reported in this Rapid Acceleration of Diagnostics – Underserved Populations (RADx-UP) publication was supported by the National Institutes of Health under Award Number (insert project grant number, including the CDCC grant number [U24MD016258] if you made use of the consortial data, data management, and/or analysis support. If your RADx-UP manuscript is derived from data we are collecting from one or more projects through the CDCC, including through RADx-UP.org or myRADx-UPHome as data assets or resources, please add this acknowledgement: This work was supported by Azure sponsorship credits granted by Microsoft’s AI for Good Research Lab.*

**Add disclaimer:** *The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.*

Prior to issuing a press release concerning the outcome of RADx-UP research, the writing team leader should notify the CDCC in advance to allow for coordination.

## E. RADx-UP Logo

When presenting RADx-UP data at scientific or public meetings, all presentations (oral and poster) are encouraged to use the RADx-UP logo and should acknowledge the National Institutes of Health using the above statement. The RADx-UP logo and presentation templates are available from the CDCC.

## F. PubMed Central Submission of Published Manuscripts

To advance science and improve human health, the National Institutes of Health Public Access Policy requires peer-reviewed articles it funds to be made publicly available via PubMed Central no later than 12 months after the official date of publication. Immediately upon acceptance for publication, RADx-UP requires lead authors to submit their final peer-reviewed manuscripts to the National Institutes of Health



Manuscript Submission (NIHMS) system and follow directives until PubMed Central assigns a PMCID number. For RADx-UP manuscripts, the primary awardees of RADx-UP grants (generally listed as a coauthor on the manuscript) remain responsible for compliance. If needed, the RADx-UP CDCC Publications Group can provide guidance.

## **G. Ensuring Timeliness of Publications and Presentations**

The Publications & Dissemination Committee and lead authors, with support from the CDCC Publications Manager, will monitor the progress of approved analysis proposals. To facilitate timely completion of research studies and dissemination of results, lead authors are expected to keep the CDCC Publications Group updated on progress status, and the CDCC Publications Manager will regularly provide updates to the Publications & Dissemination Committee.

Progress from initial analysis proposal approval to submission of the resulting manuscript should take no more than 1 year, unless otherwise agreed with the Publications & Dissemination Committee.

## **H. Publication Costs**

For manuscripts that meet the criteria as described below, the RADx-UP CDCC will consider, on a case-by-case basis, covering the cost of journal fees for RADx-UP manuscripts.

To justify for RADx-UP CC consideration, the lead author (or corresponding author) should send a statement of need to the RADx-UP CDCC Publications Group. The RADx-UP CDCC Program Director (or designee) will review the request. If the request is approved, the RADx-UP CDCC Publications Group will manage payment of the journal fees as described below.

### **The manuscript in question must meet the following criteria:**

- Approved by the Publications & Dissemination Committee;
- Primarily funded by RADx-UP, and properly reference RADx-UP grants;
- Properly reference the RADx-UP program and any contributors.

### **The RADx-UP Coordinating Center will consider paying for:**

- Open access fees;
- Journal review fees;
- Page charges.

### **The RADx-UP Coordinating Center will *not* pay for:**

- Color fees;
- Costs associated with ordering reprints.

**VI. Appendix A: Guiding Principles for Authorship on RADx-UP CDCC Publications**

1. Transparency and early discussions of manuscript authorship are critical to maintaining healthy and productive working relationships in research.
2. Authorship placement in research publications has implications for faculty promotion and tenure, especially for junior and mid-level faculty.
  - a. To promote advancement of junior faculty, senior faculty almost always concede first and last author placements to more junior faculty (with some exceptions).
3. Three main authorship placement categories are considered when deciding authors for papers, and each has a different level of scope/responsibility:
  - a. First/lead author: person drafting the paper; heavy lift on all drafts/reviews and coordination among all authors/submission.
  - b. Middle authors: contributors including those involved in data collection, funding acquisition, study design/review, and/or interpretation of data (e.g., reviewers, strategic collaborators, community partners, NIH, targeted staff); mild to moderate lift on review depending on role on the project.
  - c. Last author: typically a mid-level or senior faculty; heavy lift on the review of drafts from lead author.
  - d. Corresponding author: lead or last author; mutually agreed upon between them.
4. Selection of the target journal is driven by a balance between impact and pragmatism (e.g., need to publish quickly [pandemic, need to show a certain collaboration, timeliness for promotion and tenure]).
5. Decision-making around authorship and target journal is a short-lived process agreed upon by the lead and last author.
  - a. Lead investigators have first right of refusal to serve as lead or last (senior) author on main outcome papers (must commit to write the paper or ensure that all authors are clear on placement if another author leads writing effort).
  - b. Authorship and author order can be revisited in instances of delayed drafting of manuscripts or if required due to unforeseen circumstances.
6. The draft/review process typically follows these steps:
  - a. Lead author drafts a one-page outline of the manuscript (can be waived depending on experience of the lead author);
  - b. Lead and last author iterate until internal first draft;
  - c. Internal first draft is distributed to all co-authors;
  - d. Lead author incorporates changes from internal team and checks in with last author if major changes occurred;
  - e. For consortial publications, lead author submits revised draft to CDCC Publications Group for Publications & Dissemination Committee review;
  - f. Lead author incorporates changes from Publications & Dissemination Committee and checks in with last author if major changes occurred;
  - g. Last author signs off;
  - h. Lead author (or if requested, CDCC Publications Manager/medical editor) collects COI forms from co-authors (if required for submission) and submits manuscript to journal.

## History of Change (Since Last Version)

Section Affected	Changes Made
V. Policy	Added detail and explanation regarding the involvement of community partners on writing teams.
V. Policy	Modified wording in Technical Guidance regarding race and ethnicity, and cited a recent reference work.
V. Policy	Updated the funding acknowledgment.
V. Policy	Revised the subsection on publication costs to indicate that the CDCC will consider paying for Open Access fees.

## Approval Page

Approving Body	Signature/Date
RADx-UP Publications & Dissemination Committee	New text shared with PDC via e-mail and on monthly calls in 2023
RADx-UP Steering Committee	12/6/2023 (via individual member voting)