

Wake Forest NCORP Research Base	Standard Operating Procedures
Policy Name: Publication Guidelines	Policy Number: 11.0 – 11.6
Section: Publications 11.0	Revision Date: March 24, 2021

## 11.0 Publications

The purpose of the Wake Forest NCORP Research Base (WF NCORP RB) publications committee is to ensure WF NCORP RB study results are published in a timely manner with proper authorship inclusion and scientific merit. These publication guidelines apply to all publication types (abstracts, press releases, print- media articles/manuscripts, electronic media articles/presentations, letters, etc.) that use WF NCORP RB data and/or Central Operations Office, Biostatistical Core, Biospecimen Core or Health Equity Core resources or personnel.

1. **Manuscripts, abstracts, press releases, print-media articles/manuscripts, electronic media articles/presentations, letters, etc., related to findings and results from NCI sponsored studies referencing WF NCORP RB or using their resources must be reviewed by the Publications Committee and the NCI prior to submission or presentation.** Please send any publication, abstract or presentation for review to [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).
  - a. **Manuscripts** - Prior to initial submission to a journal, the WF NCORP RB Publication Coordinator and Committee must review the manuscript (allow 10 business days) before sending to the NCI NCORP Program Director or CCDR Program Director (allow up to 30 days). Authors are encouraged to consult the WF NCORP RB Publication Coordinator early in the manuscript development process to obtain the required acknowledgement section and obtain authorship approval to avoid delays in manuscript submission.
  - b. **Abstracts** - Should be provided to the WF NCORP RB Publication Coordinator at least 5 business days prior to initial submission to undergo WF NCORP Publications Committee and NCI review.
  - c. **Other publication types** - Review timing for publications other than abstracts or manuscripts should be discussed with the WF NCORP RB Publication Coordinator.
2. All authors will be required to review, comment and “sign-off” on the publication, abstract or presentation before submission to the WF NCORP RB Publication Coordinator. The publication first and/or senior authors are responsible for obtaining this input and sign off.
3. The Wake Forest NCORP Research Base must be cited within the manuscript (including the current grant number). In addition, all relevant federal grant numbers should be cited on the manuscript cover page, along with the clinical trials (<https://clinicaltrials.gov/>) registration number for the trial (both items provided by the RB staff). All NCORP Research Base publications should reference the NCI protocol number and/or title in the manuscript or abstract title whenever relevant to the publication.
4. To maintain an accurate and complete listing of all studies that use WF NCORP RB resources, a copy of all accepted publications (abstracts, manuscripts, presentations/posters) must be sent to the Publications Coordinator (see Table 1).

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### 11.1 WF NCORP RB Publications Committee

The Publications Committee will assist publication efforts to ensure the timely distribution of WF NCORP RB clinical research results; therefore, ensuring their accessibility for the scientific, as well as, the lay communities. The Committee accomplishes this by:

- Monitoring the progress of publications related to the WF NCORP RB;
- Reviewing all authorship assignments;
- Reviewing scientific merit.

### 11.2 Publications Coordinator

The Publications Coordinator will be the point of contact for all authors. Authors may contact the Publications Coordinator to learn about available WF NCORP RB resources to assist with publication preparation.

### 11.3 Authorship Guidelines

WF NCORP RB provides authorship to investigators who contribute significantly in one or more of the following roles: scientific development, data analysis, abstract/manuscript writing and review. In accordance with the goals of a community oncology research network, the WF NCORP RB also extends authorship to those investigators who provide scientific data through significant patient accrual, and/or clinical data and biological sample submissions.

#### 1. General Considerations

- a. The total number of authors is subject to meeting/journal policies.
- b. The acknowledgements section provided by the WF NCORP RB Publications Coordinator must be included in the submission.
- c. The WF NCORP RB Publications Committee has the authority to reassign any authorship position, including the first author, if the author(s) do not meet the deadlines described on the publication timeline. NCORP Research Bases are by definition and by NCI mandate, data sharing entities. Once published, WF NCORP RB data will become available to the public at-large and individuals hold no exclusive publication rights beyond those stated above.

#### 2. Authorship Determination and Author Order for WF NCORP RB

##### *NCORP Faculty & Staff*

- It is expected that one or both NCORP multi-PIs should be included on all study manuscripts. Other NCORP faculty and staff who substantively contributed to the design, conduct and analysis of the study and/or its data should also be included on study manuscripts where appropriate.

##### *Biostatistician(s)*

- The primary study designated biostatistician should generally be listed as second author on protocol specified analyses.
- When appropriate, additional biostatisticians may be recommended for authorship. If the primary study statistician is external to the WF NCORP RB, the designated WF NCORP RB faculty biostatistician who oversaw data capture, data monitoring, data cleaning, and who created final data sets should be included as a co-author. This individual is expected to be involved in the writing/editing of the manuscript at draft stages and to read and approve the final version.

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*Study Co-Investigators*

- Co-Investigators who appropriately contributed to the publication should be listed as co-authors.

*Accrual Authors*

- The WF NCORP RB Publications Committee, in conjunction with the first author, biostatistician and other appropriate study team co-authors, will offer co-authorship to a limited number of NCORP Site investigators based on their accrual contributions. Authorship based on accrual will be granted to institution(s) that enrolled the largest number of patients to the study (at least 2 site PIs should be listed for each primary or secondary objective manuscript). These authors are expected to be involved in the writing/editing of the manuscript and to read/approve the final version.
- The WF NCORP RB Publications Coordinator, working in concert with the Publications Committee, will identify the NCORP Community Sites with the largest number of patients to the trial. We will then contact each NCORP Site Principal Investigator to identify an appropriate author. It is expected that the NCORP Community Site Principal Investigator will generally award accrual authorship to the identified highest enrolling provider among its NCORP Community Site network of affiliates and sub-affiliates.
- The first author will be provided with the names of the accrual authors by the WF NCORP RB Publications Coordinator.

*Senior Author*

- If the Study PI is the first author of the primary outcome paper of the study, he/she may recommend a study co-investigator or one of the NCORP multi-PIs as senior author.

**11.4 Archiving WF NCORP RB Oncology Publications**

Copies of all publications, including manuscripts, abstracts and journal articles, conference proceedings, brief communications, editorials etc. should be sent upon publication to [ncorp@wakehealth.edu](mailto:ncorp@wakehealth.edu). All such articles will be entered into the WF NCORP RB publications database and copies of the articles will be retained by the Publications Committee. A list of recent WF NCORP RB publications will be available on the WAKE NCORP website.

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### 11.5 WF NCORP RB Publication Timelines

Type of publication	Timelines		
	<u>Initial Author Deadline</u>	<u>Group Review Period</u>	<u>Post Submission Author Deadlines</u>
<b>Journal Article</b>	<u>Primary and Secondary outcome manuscripts:</u> -First draft due within 6 months of data availability -Final draft due within 1 year of data availability Manuscript authors should be in early contact with the Publication Coordinator to ensure efficient review.	<u>Final draft prior to initial journal submission:</u> 1) NCORP Publications Committee (allow 10 business days) 2) NCI (allow up to 30 days) 3) Resubmitted manuscripts with substantial scientific changes made following initial review by the publication committee, should be resubmitted to the Publication Coordinator to determine if another DCP/Publications Committee review is warranted.	A PDF of the published manuscript should be submitted to the NCORP Publication Coordinator no later than 4 weeks after available.  All manuscripts arising from NIH funding must be submitted to PubMed Central <i>upon acceptance for publication</i> . This submission will be the responsibility of the Publication Coordinator or their designee if the journal does not submit the manuscript automatically.
<b>Meeting abstract &amp; National and International Presentations (please verify with Publication Coordinator if uncertain if a presentation requires review and approval)</b>	Preliminary results of major phase III trials and large definitive care cancer delivery studies should be presented at a scientific meeting within 6 to 8 months of completion of the study analysis.	<u>Final draft prior to conference submission:</u> 1) NCORP Publication Coordinator and NCI (allow 5 business days) 2) All authors should review prior to conference submission, including all NCORP Biostatisticians and NCORP ESC member(s). If the author list does not include an NCORP biostatistician or NCORP ESC member, consult the Publication Coordinator.	A copy of the accepted abstract should be submitted to the NCORP Publication Coordinator no later than 4 weeks after acceptance.
<b>Press releases, print-media articles, electronic media articles, letters, etc</b>	Please consult the Publication Coordinator for timelines.		

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**Contact information:**  
 All publications should be sent to the Publication Coordinator ([ncorp@wakehealth.edu](mailto:ncorp@wakehealth.edu)) for submission and archiving.  
 Publications Committee: [ncorp@wakehealth.edu](mailto:ncorp@wakehealth.edu)  
 PubMed Central: <https://www.ncbi.nlm.nih.gov/pmc>

## 11.6 Publication Checklist

<b>Wake Forest NCORP Publications Checklist</b>	
<b>(To be submitted with the manuscript to the publication coordinator at the time of initial review)</b>	
<b>Task</b>	<b>Done</b>
<b>Research Base Attribution</b>	
1. The Wake Forest NCORP Research Base is cited	<input type="checkbox"/>
2. All federal grant numbers are cited	<input type="checkbox"/>
3. The clinical trials registration number is included	<input type="checkbox"/>
4. The NCI protocol number and/or title is included in the manuscript or abstract title	<input type="checkbox"/>
<b>Authorship and Acknowledgements</b>	
1. Study co-investigators who have contributed to the publication have been considered/included as co-authors	<input type="checkbox"/>
2. The primary study biostatistician is included as second author on protocol specified analyses	<input type="checkbox"/>
3. Additional NCORP biostatisticians have been considered for authorship, as needed	<input type="checkbox"/>
4. Both NCORP PIs have been considered/included as authors	<input type="checkbox"/>
5. The author list includes NCORP Community Site accrual authors	<input type="checkbox"/>
6. An approved acknowledgments section is included that lists participating sites and key staff	<input type="checkbox"/>
<b>Review, Submission, and Acceptance</b>	
1. All authors have reviewed, commented, and signed-off on the publication, abstract, or presentation	<input type="checkbox"/>
2. Submit near-final draft to the Publications Coordinator for review (coordinator will submit for NCI approval)	<input type="checkbox"/>

**Reminders:**

Submit accepted abstracts and manuscripts to the Publications Coordinator with the study title and protocol number  
 Final accepted manuscript is submitted to PubMed Central.  
*Checklist is for publication author internal use.*