



# Foundation Fighting Blindness (FFB) Clinical Consortium

## Manuscript Development Process

The Governance Document contains the overarching editorial policies for the FFB Clinical Consortium. This document is intended to expand on those policies and provide more details of the Operations Committee's process for selecting writing committees and writing manuscripts.

### Version 1.0

**Date: October 3, 2019**

Version History

VERSION NUMBER	AUTHOR	APPROVER	EFFECTIVE DATE	REVISION DESCRIPTION
1.0	A.Ayala	Operations Committee	20 FEB 2019	First version
2.0	A.Ayala	OC approved change on 10-2-19 call	03 OCT 2019	Site PI signs off on both the manuscript and the acknowledgement listing, for all manuscripts
3.0	S. Hatch	A. Ayala	06 JUN 2025	Details author listing standard for manuscripts

## 1.0 Writing Committee (WC) Selection Process

1. Step 1: CC creates a starting list to be reviewed
  - a. Primary papers:
    - i. Decide whether or not to poll investigators for interest, or just review list of highest recruiting investigators for the study.
  - b. Secondary Papers:
    - i. Poll all eligible investigators (i.e., those who enrolled at least one participant in the given protocol) for interest - if paper topics/ideas are available, can also ask to indicate preference.
2. Step 2: OC reviews the list of options and assigns as follows (OC may get advice from the EC)
  - a. WC members:
    - i. Select/prioritize based on expertise on the topic, contributions to study (e.g. recruitment), willingness to commit to responsibilities (see below)
    - ii. ***For secondary papers*** where interest poll was gathered - Everyone indicating interest should be offered placement on at least one WC (may not guarantee their topic of choice).
    - iii. Also CC staff: The lead statistician is always on the WC. The senior statistician and/or the project director may also be on the WC depending on level of contribution.
  - b. Lead author:
    - i. Select/prioritize based on expertise on the topic, contributions to study (e.g. recruitment), willingness to commit to responsibilities (see below)
    - ii. ***For primary papers*** this will typically be the study chair.
  - c. Author listing:
    - i. The standard for listing writing committee members is the following. This can vary (e.g., senior statistician is more heavily involved in writing listed higher, multiple/co-leads listed as 1st/2nd author, specialty expert listed as senior/last author, etc.).
      1. 1st - Lead author
      2. 2nd- Lead statistician
      3. Remaining writing committee members in alphabetical order
      4. Study chair should be listed as the senior/last author, if they are not the lead author
3. Step 3: CC formally invites the WC and lead author
  - a. Ask for confirmation and agreement to responsibilities (see below).
  - b. Note that member may be removed from the WC if responsibilities are not met.

## 2.0 Writing Committee and Lead Author Responsibilities

1. WC responsibilities:
  - a. According to the FFB Clinical Consortium Governance document (which follows the to the International Committee of Medical Journal Editors (ICJME) recommendation for authorship) --- *Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published.*
2. Lead author responsibilities :

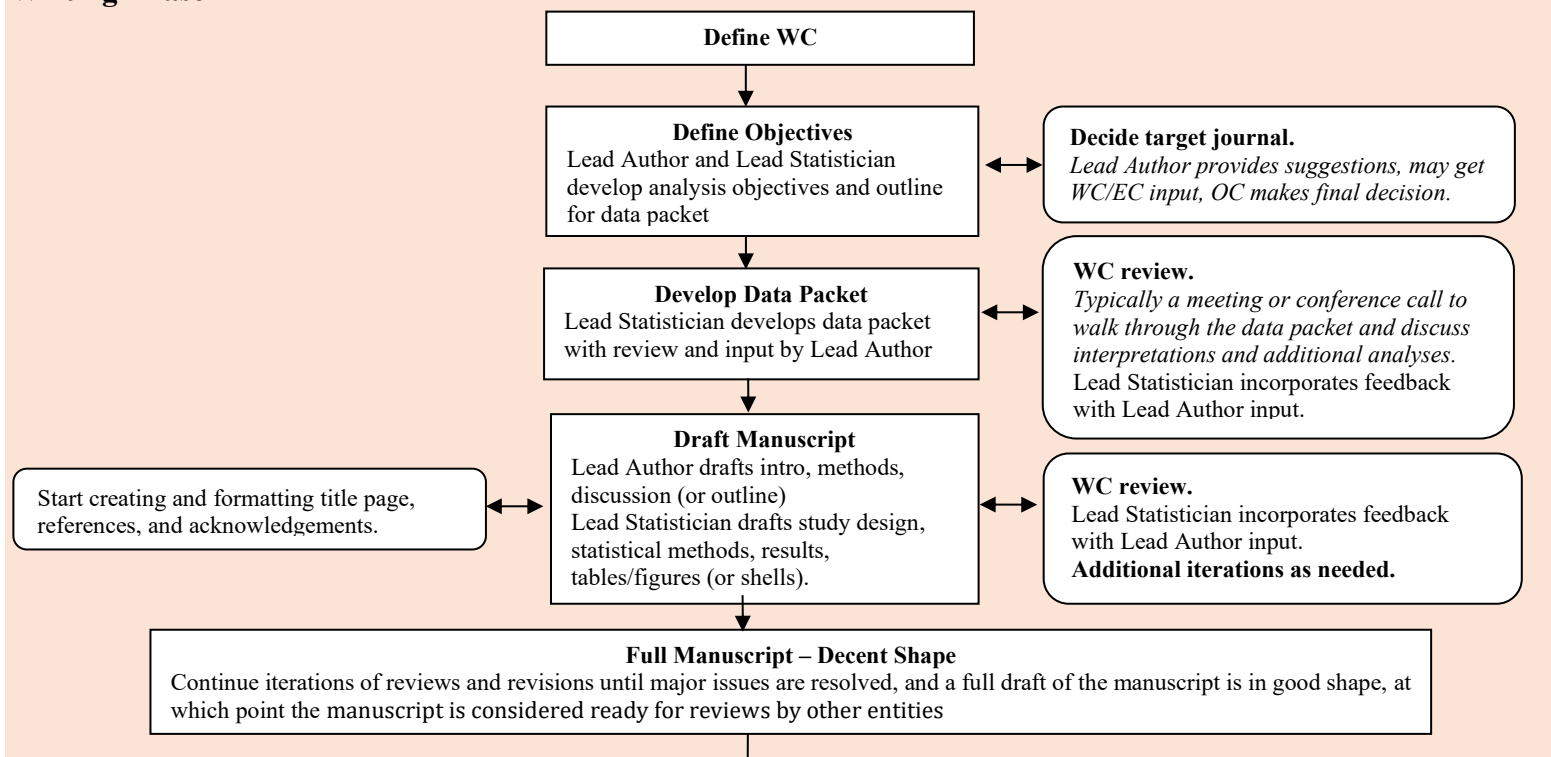
- a. Lead the overall writing efforts in parallel with the CC lead statistician.
- b. Draft portions of the paper, often including but not limited to the introduction, clinical or technical portions of the methods (CC will write study design and statistical methods), and discussion.
- c. Lead the review of comments/edits and revision of drafts in parallel with the CC lead statistician.

### 3.0 Manuscript Writing Process

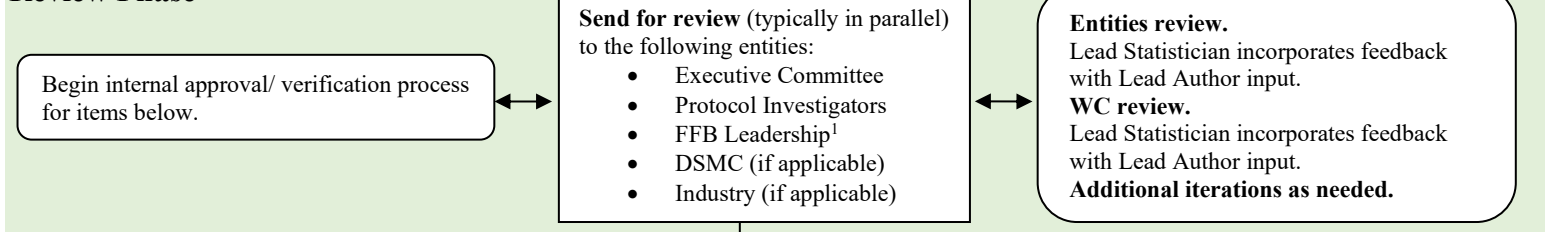
See flow chart for overview of the typical process. Each paper has its unique requirements and challenges, so the exact steps may vary.

#### Manuscript Writing, Review and Approval Flow Chart

##### Writing Phase



##### Review Phase



##### Approval/Verification Phase

