GENERAL PROCEDURAL POLICIES

CVM EXTERNAL COMMUNICATIONS CLEARANCE POLICY AND PROCEDURES

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Responsible Office: Office of the Center Director, Executive Programs
Date: 11/1/2005

CVM EXTERNAL COMMUNICATIONS CLEARANCE POLICY AND PROCEDURES

CVM EXTERNAL COMMUNICATIONS CLEARANCE POLICY

It is the policy of the Center for Veterinary Medicine that:

1. information communicated to the public by CVM staff must be accurate, consistent, and well written;

2. communications from CVM, regardless of the method of dissemination, are scientifically and technically accurate and are consistent with CVM policy;

3. information communicated to the public by:

   (a) publications in scientific/medical journals,

   (b) www postings,

   (c) speeches,

   (d) abstracts and posters for meetings,

   (e) CVM updates, and

   (f) other communications

   must be cleared through the appropriate CVM clearance procedures (see attached);

4. this policy will *not* apply to:

   (a) guidance documents,

   (b) legal notices prepared for the Federal Register, and

   (c) other documents issued to meet legal requirements;

5. CVM management encourages staff to share information that will benefit our public and animal health mission. This includes, but is not limited to, publishing articles in scientific or professional journals, taking advantage of opportunities to speak on CVM issues, and through publication of general communications such as CVM Updates;

6. collaboration within and outside CVM is encouraged;

7. the clearance process will be efficient and time sensitive to facilitate timely publication and minimize frustration of all parties;

8. for the purposes of consistency of policy and for dissemination of scientific information, it is desirable for external communications to be archived and available to CVM employees and to the general public; and

9. CVM policy will be consistent with FDA policy on manuscript clearance.

CVM EXTERNAL COMMUNICATIONS CLEARANCE PROCEDURES

I. GENERAL CONSIDERATIONS FOR ALL COMMUNICATIONS

A. Representation

1. Speaking or writing only as a representative of your specialty e.g., as a toxicologist or a beekeeper or a veterinarian speaking to the Pony Club about lameness:

   These would be considered non-work-related communications subject to the following:

   a. Prepared and presented on own time

   b. If identified/introduced as an FDA employee, must include disclaimer, "This speech/article was [written, edited] by [employee's name] in [his or her] private capacity. No official support or endorsement by the FDA is intended or should be inferred."

   c. No need for supervisory concurrence

2. Speaking or writing as an official representative of FDA e.g., as a team leader giving a presentation to the AVMA about the drug approval process:

   For work-related communications the following conditions apply:

   a. Written on government time

   b. In accordance with FDA policies

   c. Clearance through the Office level, or as specified in the following procedures

   d. Use the CVM Communication Clearance Form

   e. After approval, submit the document for archiving

B. Authorship

1. Fast track Communications: Authorship is not normally recognized for CVM Updates, worldwide web postings, or other similar communications.

2. Speeches: Authors should follow established academic conventions for citations and acknowledgements.

3. Posters, Abstracts, and Peer-reviewed Research:

   Manuscripts originating at the CVM Office of Research should follow the procedures described in the Office of Research Policy and Procedures Manual. All other CVM manuscript authors should complete the CVM Authorship Assignment Form. In addition, the following applies to all scientific communications, oral and written, of experimental results and their interpretation.

   a. In general, authors must agree to the content of and take responsibility for their manuscript. Only those who contributed directly to the intellectual content of the manuscript should be included in the list of authors.

   b. Contributions may be in any of the following categories: conceived or planned the work leading to the manuscript, participated significantly in the analysis of the results, wrote or significantly revised the manuscript's intellectual content, or approved the manuscript in its final form.

   c. Those who have contributed to the manuscript through technical work, organization of data and other associated activities should be acknowledged, with their permission.

II. FAST TRACK COMMUNICATIONS (CVM UPDATES, WWW POSTINGS, ETC.)

These are time-sensitive communications because they deal with an issue of immediate concern, or because they are linked to a particular event or date. Usually these are general communications for a broad audience.

A. Scope

CVM Updates; introductory language used only on CVM web pages; short lead time speeches; Commissioner's briefings; prepared statements to the Press.

B. Clearance

1. CVM Updates – The Center Director or designee
2. CVM Web pages – The Office Director primarily in charge of the content. In some cases, clearance from the Agency or Department may be required.
3. Short lead time speeches – Same clearance as for other speeches
4. Commissioner's briefings – Center Management Team (CMT) member and then FDA Executive Secretariat
5. Prepared Statements to the Press - The Center Director or designee

C. Procedures

1. CVM Updates (to put information in the public domain to generate interest)
   a. Draft written by subject matter expert or member of the communication staff
   b. If written by communication staff, then checked by subject matter expert
   c. Post on the CVM website in the "What's New" section for 30 days
   d. Post on the CVM website in the Updates section for long term availability
   e. Notify members on email list (list serve) of posting

2. CVM Web pages

   The procedures for document posting are described in draft Standard Operating Procedure HP110.00. (*Contact Joanne Kla*). In general,

   a. The information provided must be approved for release to the public and cleared for posting
   b. Documents for posting should be in the correct electronic format and submitted to the CVM Web Manager for review and quality control
   c. The Web Manager then will forward the document to the Webmaster for posting
   d. Pre-approved monthly or routine updates of existing information (e.g., FOI Summaries, Feed Mill Listings, Vacancy Announcements and the CVM Telephone Directory) can be submitted directly to the Webmaster.

3. Short lead time speeches

   When there is a legitimate need to get a presentation cleared quickly, the procedures established for speeches should be followed, but optional steps should be omitted and timeframes should be shortened sufficiently to meet the deadline.

4. Commissioner's/Secretary's briefings
   a. Draft briefing prepared by subject matter expert(s)
   b. CMT member reviews and signs off to complete in-house clearance
   c. Briefing materials go from CVM Executive Secretariat to FDA Executive Secretariat prior to briefing

5. Prepared Statements to the Press (Reaction to questions – short turnaround time)
   a. Text drafted by Communications Staff
   b. Subject matter expert(s) consulted as needed
   c. Reviewed and signed off by Center Director or designee
   d. Sent to Office of Public Affairs at Parklawn to respond to consumer or press inquiries that come in via telephone, email, or print.

III. NON-PEER-REVIEWED COMMUNICATIONS

A. Scope

Speeches, posters, abstracts, and non-peer-reviewed publications, such as brochures, articles for lay journals, and non-peer-reviewed articles for professional journals.

B. Clearance

Clearance is generally through:

1. Team Leader of each participant
2. Division Director of each participant
3. Office Director of each participant
4. CMT-level presentations and publications should be cleared as appropriate, by CMT and archived.

C. Procedures

(SEE Communications Approval flow chart)

1. Preparation

It is the author's responsibility to prepare the speech, poster, or other publication in the appropriate format and in accordance with applicable CVM policy guidelines.

See the authorship guide under Section I.B.

2. Review

The need for and extent of speech/poster/manuscript review will be determined by the author and his/her immediate supervisor. They will determine together the person(s) to review the communication.

The Team Leader and the Division Director review scientific content. Their reviews should focus on the accuracy of the statements and assertions, the soundness of the conclusions, etc. The Office Director[1] reviews the manuscript for policy implications. These review functions are not mutually exclusive, but indicate the main emphasis of their particular review.

Both the Office Director and the Division Director may solicit reviews from other individuals. However, only the Team Leader, Division Director, and the Office Director sign the CVM Communication Clearance Form.

[1] For the purposes of these procedures, "Office Director" refers to the Office Director or his/her designee. The "Division Director" refers to the Division Director or his/her designee.

Team Leaders, Division Directors, and Office Directors have 10 working days to return comments on a manuscript to the author. The Division Director and Office Director reviews should be done concurrently. All comments must be considered and addressed by the author.

The Office Director informs the author and the Division Director whether the speech/poster/manuscript is acceptable as written, acceptable with revisions, or held until a more extensive review/consultation is completed. Presentation to the public must await receipt of the signed CVM Communication Clearance Form.

D. Forms

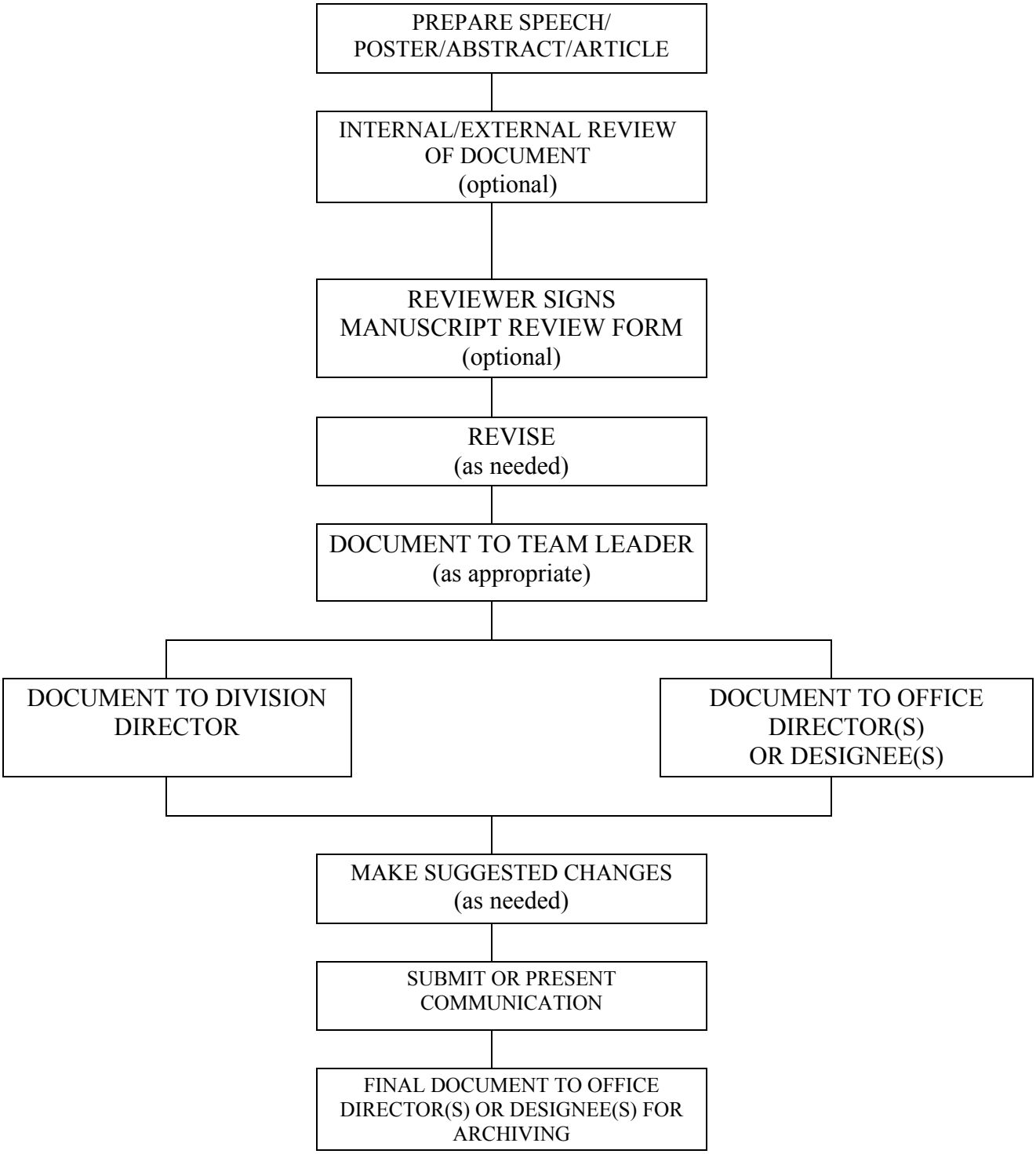
1. CVM Communication Clearance Form
2. CVM Authorship Assignment Form (optional)

E. Archiving

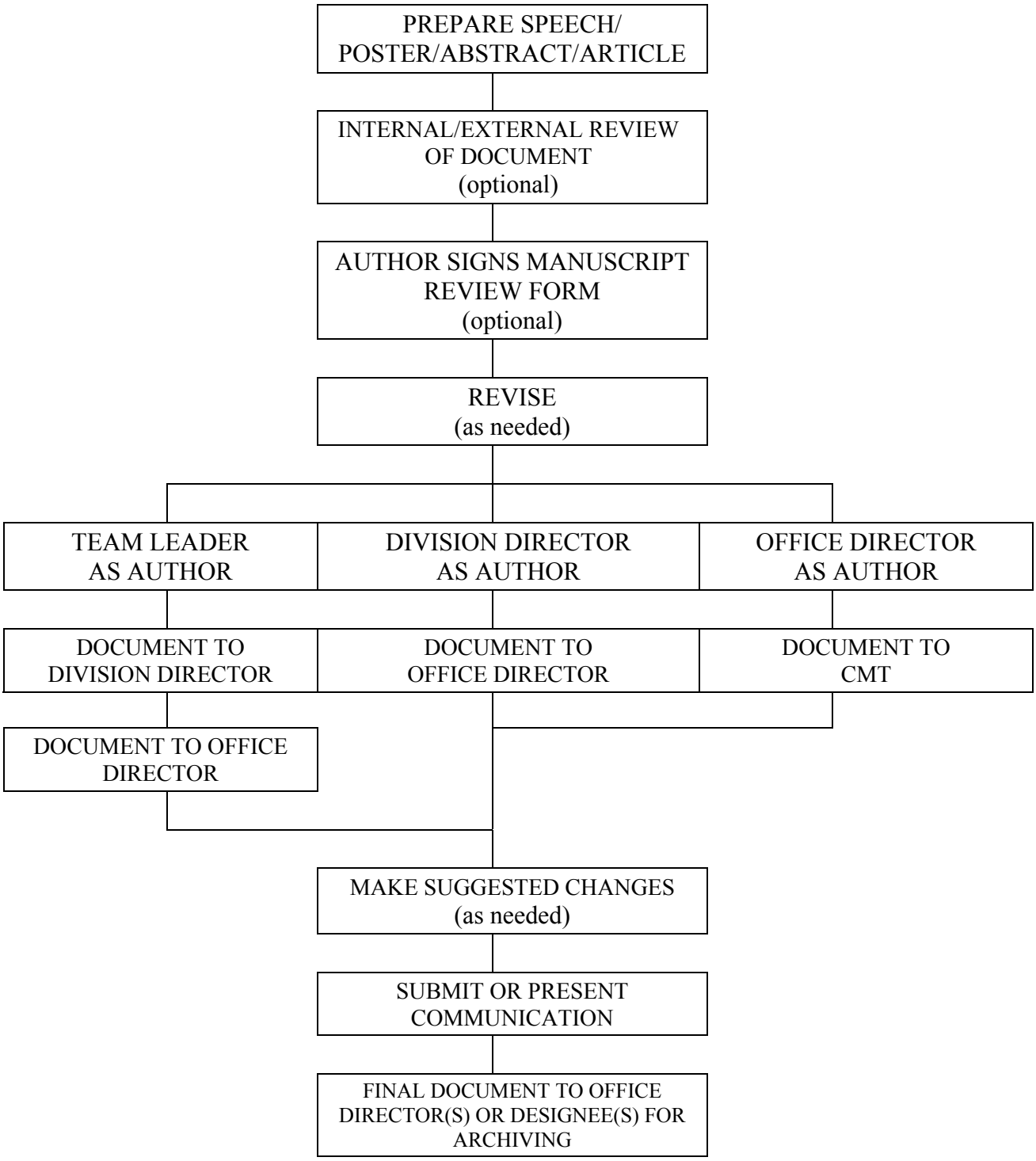
Final documents should be submitted electronically to the Office Director(s) or designee(s) to be archived.

1. Speeches should be submitted after they have been presented. PowerPoint presentations should be as presented.
2. Posters and abstracts should be submitted once they have been approved.
3. Non-peer-reviewed articles should be submitted in their published form with the publication's citation included.

COMMUNICATIONS APPROVAL FLOWCHART
For Speeches/Posters/Abstracts/Non-peer-reviewed Articles
For Reviewers



COMMUNICATIONS APPROVAL FLOWCHART
For Speeches/Posters/Abstracts/Non-peer-reviewed Articles
For Managers



IV. PUBLICATION OF PEER- REVIEWED RESEARCH

A. Scope

Peer-reviewed laboratory and epidemiology research for publication in scientific journals. This includes intra-center and intra-agency collaborative efforts and collaborations with external organizations (other government agencies and universities).

B. Clearance

1. Research done by the CVM Office of Research - The specific clearance procedures used by the Office of Research (OR Policy and Procedures Manual) are incorporated into this section by reference. Scientists conducting studies at the Office of Research should use the OR procedures.

2. OD, ONADE, and OS&C research done in collaboration with the Office of Research – Scientists who collaborate with the Office of Research scientists should follow OR Policy and Procedures. Also, they should keep their supervisors, as appropriate, aware of their research activities and must seek their approval of manuscripts for publication.

3. OD, ONADE, and OS&C research independent of the Office of Research - The manuscript review and sign-off is as follows:

   a. internal data reviewer (optional)
   b. external reviewer (optional)
   c. Quality Assurance Unit (QAU) as appropriate
   d. Team Leader of each participant in the research
   e. Division Director of each participant in the research
   f. Office Director of each participant in the research

4. Collaborative research with an organization outside of CVM

   On occasion, CVM scientists are involved in research projects with scientists from other institutions. All manuscripts resulting from such research collaboration must be reviewed by the Team Leader, Division Director and the Office Director. Data generated by CVM scientists from collaborations may be subjected to both the internal review procedures and data audit procedures of the collaborating institution. Changes required by all CVM approving officials must be incorporated into the manuscript, especially if there are policy implications. If the external co-authors are unwilling to agree to the changes, then the CVM scientist(s) must decline authorship.

C. Procedures

1. Manuscript Preparation

a. Author's Responsibilities

It is the author's responsibility to prepare the manuscript in accordance with the journal format and applicable CVM policy guidelines.

See the authorship guide under Section I.B.

b. Data Presentation

Authors should use spreadsheets and electronic data capture as much as possible for data requiring calculations or transformations. Furthermore, the author should standardize the manner in which the data are presented. This will facilitate the data audits by both the internal reviewer and the Quality Assurance Unit (QAU) (if applicable). It is recommended that a separate sheet containing an explanation of how the data were 1) generated, 2) recorded, 3) reduced, 4) transformed, and 5) analyzed will accompany the data. The equations should also be included on this sheet. If a data reviewer (internal or QAU) cannot interpret the results and how they were derived, the manuscript and data may be returned to the author for clarification. The manuscript may then be re-submitted as a new submission.

In writing inferences from Epidemiological data and surveillance data, authors should review data to ensure that contents avoid biases, confounding or interaction and in addition, test the validity of the data before any significance inferences are made.

All comments are returned to the primary author for correction prior to obtaining a final concurrence from the Division Director for signature. The manuscript may then be forwarded to the Office Director for concurrence.

2. Manuscript Review

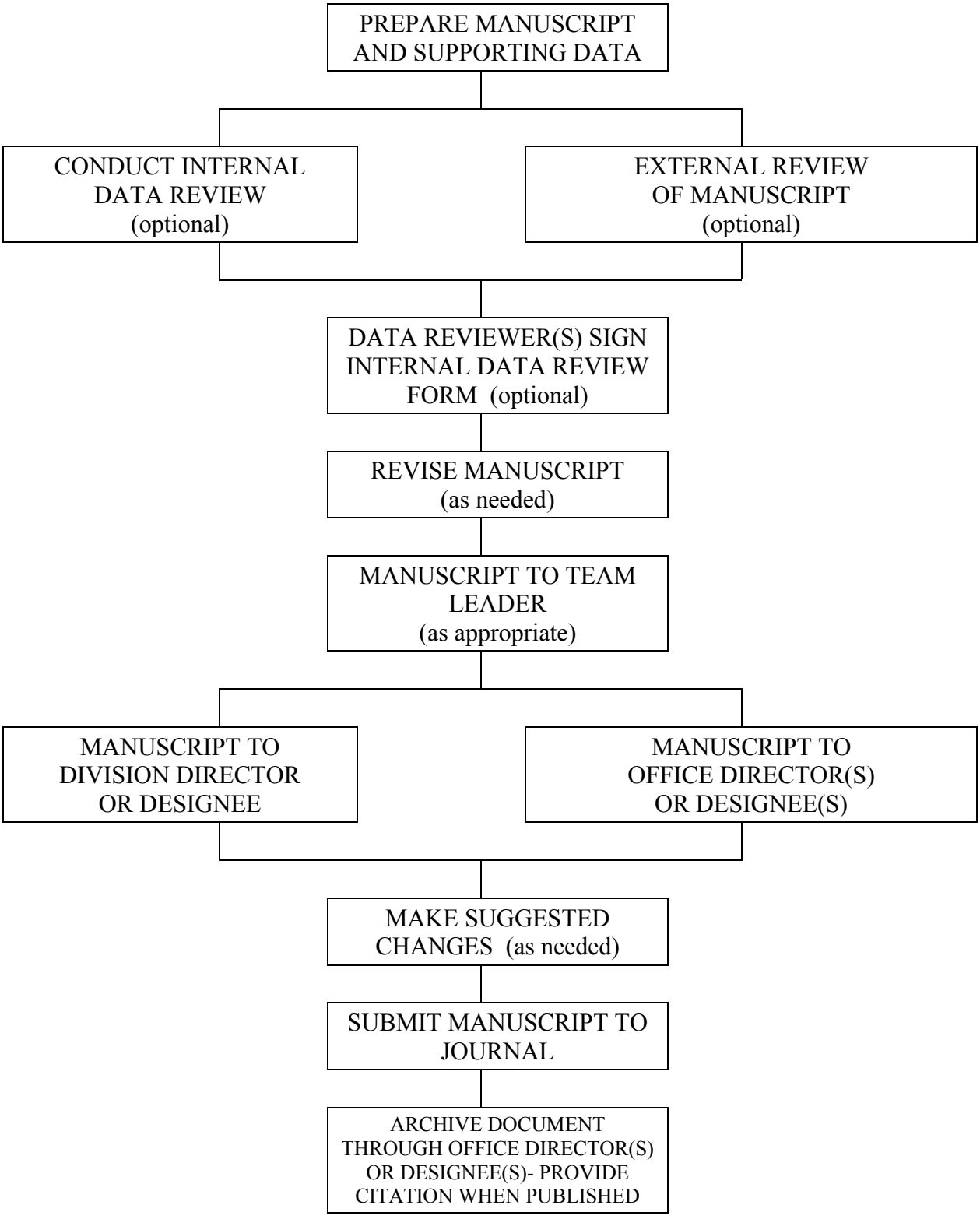
(SEE Manuscript Approval flow chart)

a. Internal Review (optional)

If the primary author is from CVM, then it is recommended that an internal review of the data be conducted and the internal data review form be completed. The extent of the review will be determined by the author and his/her immediate supervisor.

The supervisor, in consultation with the author, will select the person to review the data. Upon completion of the review, the reviewer and author will attest to the completion of the review by signing the Manuscript Review Form, which must accompany the data.

MANUSCRIPT APPROVAL FLOWCHART
for Peer-Reviewed Research



b. External Review (optional)

It is recommended that the author solicit an external review of the manuscript from qualified colleagues of his/her choosing. This is solely the purview of the author. The purpose of this review is to solicit comments on the scientific quality of the manuscript from other scientists working in this field. Upon completion of the review, the external reviewer should complete the Manuscript Review Form. This form, along with the author's responses to this review, should accompany the manuscript when submitted for office review.

c. Office Manuscript Review

The Team Leader and the Division Director review the scientific content of the manuscript. Their reviews should focus on the accuracy of the statements and assertions, the soundness of the conclusions, etc. The Office Director[2] reviews the manuscript for policy implications. These review functions are not mutually exclusive, but indicate the main emphasis of their particular review.

Both the Office Director and the Division Director may solicit reviews from other individuals. However, only the Team Leader, Division Director, QAU (if applicable), and the Office Director sign the manuscript approval form.

Team Leaders, Division Directors, and Office Directors have 10 working days to return comments on a manuscript to the author. The Division Director and Office Director reviews should be done concurrently. All comments must be considered and addressed by the author. The author is responsible for informing all parties of the response(s).

The Office Director informs the author and the Division Director whether the manuscript can be submitted as written, submitted with revisions, or held until a more extensive review/consultation is completed. Submission to the journal must await receipt of the signed manuscript approval form.

The author is responsible for relaying the status of the manuscript to all coauthors and supervisors.

3. Quality Assurance Data Audit (for research done at CVM only)

[2] For the purposes of these procedures, "Office Director" refers to the Office Director or his/her designee. The "Division Director" refers to the Division Director or his/her designee.

GLP studies always require a complete data audit. A non-GLP study may be subjected to a spot check QAU audit at the discretion of the Director of the Office of Research. If a QAU audit is required, the Office of Research Policy & Procedures Manual GEN-012 should be followed.

4. Human Subject Protection

   Research involving human subjects, as defined by 45 CFR 46, must be documented to be in compliance with these regulations. Documentation must accompany the proposed article when presented for clearance by the Office Director or the Center Director. The required documentation is a copy of the exemption or approval letter signed by the FDA's Institutional Review Board chairperson.

D. Forms

   a. Manuscript Review Form - optional

   b. CVM Communication Clearance Form - required

   c. CVM Authorship Assignment Form – required

E. Archiving

   At the time that the article is actually published, the final document should be submitted electronically to the Office Director(s) or designee(s) to be archived. The article should be in the final published form. A citation or link to an online journal may be supplied instead. The article itself is preferred.

V. RESOURCES AND REFERENCES

A. Quality Assurance Unit at the CVM Office of Research (*contact O.J. Cartwright at the Office of Research*)

B. CVM Staff College for training in grammar, technical writing, PowerPoint presentations, etc. http://cvmstaffcollege.cvm.fda.gov/kc/login/login.asp?kc_ident=kc0001

C. FDA Policy of Review and Clearance of Articles to be Published in Scientific or Professional Journals. This document can be found on the 'O' Drive in the _RESOURC directory.

D. Office of Research Policy & Procedures Manual. OR's 'S' Drive.

E. The archive for CVM Communications is located on the FDA Science First page at http://first.fda.gov/speech/ . A help text document for using the archive is provided as an appendix to this document.

VI. FORMS

A. Manuscript Review Form

B. CVM Communication Clearance Form

C. CVM Authorship Assignment Form

MANUSCRIPT REVIEW FORM

<table>
<tr><td colspan="3">☐ INTERNAL REVIEW ☐ EXTERNAL REVIEW</td></tr>
<tr><td colspan="2">MANUSCRIPT TITLE</td><td></td></tr>
<tr><td colspan="2">Author(s)</td><td></td></tr>
<tr><td colspan="2">Reviewer's Name</td><td></td></tr>
<tr><td colspan="2">Title</td><td>Proposed publisher/Journal</td></tr>
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[ ] Acceptable as is
[ ] Acceptable with revision(s)
[ ] Unacceptable</td></tr>
<tr><td>Reviewer Signature</td><td>Date</td></tr>
<tr><td colspan="2">Primary Author Signature</td><td>Date</td></tr>
<tr><td colspan="3">Comments (Attach additional sheets as needed):</td></tr>
</table>

CVM COMMUNICATION CLEARANCE FORM

Date of Request			Date Received
Contact Person:			
Title:			
Author(s):			
Journal Article _____	Name of Journal		
Book Chapter _____	Title of Book		
	Meeting Sponsor	Date	Place
Abstract for Meeting ____			
Symposium ____			
Proceedings ____			
Speech Only ____			
Other _____			
IF CLEARANCE IS REQUESTED TO MEET DEADLINE, GIVE DATE _____			
FOR OFFICE OF THE CENTER DIRECTOR:			
Title	Signature		Date
Center Director (or designee)			
FOR ALL OTHER OFFICES:			
Title	Signature		Date
Team Leader			
Division Director			
Office Director			
Copy to Office Director(s) or designee(s) for filing to the electronic archive ☐			

CVM AUTHORSHIP ASSIGNMENT FORM

Title of Manuscript	
Principal Author:	Date:

I have discussed the authorship of the above document with all of the participants of this study listed in the protocol and have informed each of them if he or she will be listed as a coauthor of the document. I have given each of the coauthors a copy of the document and allowed them to review and comment upon it. I have listed these coauthors below in the order in which their names will appear on the document. Their signatures show that they agree to be coauthors of the document in the order listed and that they accept the responsibilities that authorship entails.

Principal Author Signature:	Date:

Coauthor(s)	Signature	Date
1.		
2.		
3.		
4.		
5.		

(Multiple copies may be used if coauthors are not all in one location or if more signature space is needed).

The following study participants declined authorship or had limited contributions to the research described in this document. Their signatures indicate concurrence with their non-author assignment.

Other Contributors	Signature	Date

Approval
Signature of one Division Director is sufficient if all participants are in that division. Otherwise, all applicable Division Directors' signatures are required for clearance.

Division	Signature	Date