
Manual of Standard Operating Procedures and Policies

General Information - Review

Interoffice Consultative Review Procedures

SOPP 8001.1

Version #1

Date: Nov. 21, 1996

1. Purpose

Describes the procedures for requesting and tracking interoffice consultative reviews within the Center, the responsibilities of consulting reviewers, and the procedure for assigning credit for these reviews.

2. Applicability

This policy addresses consultative review only.

3. Definitions

Consult

A review activity in which advice on a specific question or issue raised in a submission is requested by the primary reviewer, in consultation with the committee chairperson or supervisor as appropriate. The consultative review will be used to assist the primary reviewer in taking appropriate regulatory action.

Originator

The individual requesting the consultative review. This person may be the primary reviewer or the CSO/Division Coordinator or the committee chair.

4. Background

During regulatory review, the need frequently arises to obtain consults with expert reviewers in other Offices within the Center. The procedures described in this document were developed with the following considerations in mind:

- All consult reviewers should be held accountable for their timely and complete response to consult requests and should in turn be credited for their input.
- The Document Control Center (DCC) should be able to track the physical location of any regulatory submission including those routed for consultative review.
- Reviewer communication and collaboration must not be constrained by the process and delays caused by the process should be minimal.

5. Policy

Consultative reviews are a critical part of the managed review process. All consulting reviewers shall be held accountable for, and shall receive credit for, thorough and timely expert reviews of Investigational New Drug Applications (INDs), IND amendments, Master Files, Investigational Device Exemptions (IDEs), IDE amendments, Biologics License Applications (BLAs), BLA supplements, Product License Applications (PLAs), PLA supplements, Establishment License Applications (ELAs), ELA supplements, New Drug Applications (NDAs), NDA supplements, PreMarket Approval Applications (PMAs), and 510ks, as well as any other information related to a regulatory action (e.g., promotion and advertising).

Every effort should be made to identify the need for a consultative review early in the review process, for example, at the pre-pivotal trial meeting or at the pre-PLA meeting. The need for extensive consultations is often best handled by appointing the person to the review committee. Refer to Office-specific procedures concerning requesting the appointment of a full committee member from another Office within CBER.

6. Procedures

Initiation of an IND/IDE Consultative Review

Any reviewer may determine the need for a consult on an original IND/IDE or amendment. The assigned reviewer, with concurrence of his/her branch/laboratory chief or division director (see Office-specific procedures), should contact the director of the consulting division to insure that the consultative review can be completed in a timely manner and to identify the consulting reviewer.

Upon agreement with the consultative review division that the consult can be completed in a timely manner, a consultative review request memo (CRR) should be completed and forwarded to the director of the consultative review division (appendix 1). The CRR memo should accompany the routed IND copy if possible. It is the obligation of the request originator to state, in writing, the subject of the consult, the specific sections of the application to be reviewed, and the intended scope of that review. Specific questions or issues to be addressed should be clearly identified in the memo. The memo should also provide a due date for the completed review and state that the consultative review should be routed back to the originator through DCC.

Sending the submission for consultative review and notification to DCC

If the original reviewer is finished with the submission, the document should be returned to DCC along with a DCC CHANGE/ACTION REQUIRED NOTICE and the CRR memo for routing to the consultative reviewer.

- The DCC CHANGE/ACTION REQUIRED NOTICE should request that DCC forward the document and the CRR memo to the consultative reviewer.
- The location of the consultative reviewer in CBER, including the building and room number, should be identified.

If the original reviewer is not finished with the submission the originator will check BIMS to determine if an unrouted copy is available. If a copy is available, a DCC CHANGE/ACTION REQUIRED NOTICE requesting routing of the copy to the consultative reviewer should be sent to DCC, or the request may be sent to DCC by electronic mail (using the DCCREQ address) as follows:

TO: DCCREQ

CC: CSO and/or reviewer(s) as appropriate

SUBJECT: CONSULTATIVE REVIEW REQUEST

Please route IND (number), Amendment (number), submitted on (date) to (name and division) for CONSULTATIVE REVIEW.

In both cases, a copy of the CRR should accompany the submission to be sent to the consulting reviewer.

It is the responsibility of the originator to forward a copy of the CRR to DCC to be attached to the submission prior to it being forwarded to the consulting reviewer. Alternatively, the CRR can be forwarded directly to the consulting reviewer.

- If no additional copies are available for routing, the originator should arrange to have a copy made of relevant portions of the submission or to request additional copy(ies) from the sponsor. The originator should send the copy of the submission, the CRR memo and a DCC CHANGE/ACTION REQUIRED NOTICE, if appropriate to DCC with instructions for routing to the consulting reviewer.
- If an additional copy has been requested, the sponsor should be notified to include a cover letter with the submission stating that the submission is an additional requested copy.
- A routing request should be sent to DCC by electronic mail to facilitate routing when the additional copy is submitted.
- A copy of the CRR should be sent to the consulting reviewer by the originator. If the original reviewer wants to "lend" his/her copy temporarily to the consulting reviewer, the originator should send a DCC CHANGE/ACTION REQUIRED NOTICE or an electronic mail message to DCC stating that an official copy of the submission has been temporarily transferred to another division:

TO: DCCREQ

CC: CSO and/or reviewer(s) as appropriate

SUBJECT: CONSULTATIVE REVIEW REQUEST

The (COLOR) copy of IND (number), Amendment (number), submitted on (date) has been sent to (name and division) for CONSULTATIVE REVIEW.

The originator should attach the CRR memo to this copy.

Entry of Data into BIMS

DCC enters the names of consulting reviewer(s) into BIMS, and routes copies as appropriate. Consulting reviewers are listed as type "R" in BIMS. BIMS allows the same copy to be routed to two reviewers at the same time if one of the reviews is type "R". Thus, "loaned" copies can be tracked in BIMS.

Initiation of a BLA/PLA/ELA/PMA/510k Consultative Review

Any assigned reviewer may notify the committee chair of need for a consult on an original application or a supplement. The committee chair, with the concurrence of his/her division director or designee (refer to Office-specific procedures), should contact the director of the consulting division to insure that the consultative review can be completed in a timely manner and to identify the consulting reviewer. In addition, the committee chair should notify the regulatory coordinator responsible for the file. Upon agreement with the consultative review division, the CRR memo including specific questions or issues to be addressed should be completed and forwarded to the consultative review division through DCC accompanied by a DCC CHANGE/ACTION REQUIRED NOTICE. The chair should assure that DCC routes appropriate sections of the submission to the consultant. Alternatively, an electronic mail message may be sent to DCC (using the DCCREQ address) as follows:

TO: DCCREQ

SUBJECT: CONSULTATIVE REVIEW REQUEST

Please route BLA/PLA/ELA/PMA/510k Reference (number), Supplement (number), Volume(s) (number), submitted on (date), to (name and division) for CONSULTATIVE REVIEW.

If an additional copy of the submission is not available in DCC, the originator should request an additional submission from the applicant. Any additional copy(ies) supplied by the applicant should be sent to and distributed by DCC.

- If an additional copy has been requested, the applicant should be notified to include a cover letter with the submission stating that the submission is an additional requested copy.
- A routing request should be sent to DCC by electronic mail to facilitate routing when the additional copy is submitted.
- A copy of the CRR should be sent to the consulting reviewer by the originator.

Responsibilities of a Consulting Reviewer

All consultative reviews will be type-written review memoranda. All reviews shall include a brief summary describing the portion of the submission which was reviewed. The consulting reviewer should perform a complete review of those areas specified by the originator. If the consulting reviewer does not have the expertise to address the specified areas requested, the originator shall be immediately notified. "No comment" is not an acceptable review response.

The consulting reviewer is responsible for obtaining the appropriate clearances/sign-off, as specified by Office-specific procedures. The consulting reviewer shall then forward the original review, along with the CRR memo and the reviewed submission, directly to DCC for inclusion in the official application file, and forward a copy of the review directly to the originator. The originator is responsible for sending copies of the review to the regulatory coordinator, and the committee chairperson.

Every effort shall be made to meet the request date as stated in the CRR memo. If this date cannot be met, the consulting reviewer should immediately notify the originator.

Tracking Review Status and Review "Credit" for Consults

The standard BIMS reports on pending IND, IDE, or MF submissions will indicate which reviewers are doing consultative reviews, and whether those reviews have been completed. Special reports can be generated to provide information on the number of consults by component and reviewer.

Consultative review requests for BLAs/PLAs/ELAs/PMAs/510ks will be forwarded to the applications division in the Office with product responsibility or the Office of Establishment Licensing and Product Surveillance for data entry into the RMS system. Consulting reviewers will be listed in the license committee field and be distinguished with a suffix "CON".

Handling Consult Delays

Problems with specific consultative review requests, including non-compliance with due dates or unacceptable/incomplete reviews, should initially be resolved by the reviewers and the committee chairperson. If unresolvable at that level, problems should be brought to the attention of the appropriate division directors.

7. Effective Date

November 21, 1996

8. Appendix

[Consultative Review Request Memorandum \(PDF, 14 KB\)](#)

Note: Documents in PDF format require the [Adobe Acrobat Reader®](#).

9. History

Written/Revised	Approved	Approval Date	Version Number	Comment
E. Gordon / D. Henderson	Rebecca Devine	November 21, 1996	1	OD-R-11-96 reissued as SOPP 8001.1 in May 1997. No change to Guide content.

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