CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION
and
OFFICE OF IN VITRO DIAGNOSTICS AND RADIOLOGICAL HEALTH
Standard Operating Procedures
Review of Investigational Device Exemption (IDE) Application-Specific Issues

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1. Purpose

The purpose of this document is to describe the process for initiating Clinical Trial (CT) Director[1] and CT Program review and collaboration to resolve Investigational Device Exemption (IDE) application-specific issues that persist after multiple review cycles.

2. Background

Part of CDRH's vision includes that patients in the U.S. have access to high quality, safe, and effective medical devices of public health importance first in the world. To that end, CDRH has identified as a strategic priority the strengthening and streamlining of the clinical trial enterprise so that medical device clinical trials are conducted in the U.S. in a timely, efficient, and cost-effective manner, while maintaining appropriate patient protections. Review of IDEs is challenging given the short review timeline and the significant clinical, statistical, scientific and engineering expertise necessary to make decisions on the approvability of a study. CDRH seeks to develop processes to improve efficiency, consistency, and predictability of the IDE process to reduce the time and number of cycles needed to reach appropriate IDE approval for medical devices in general and for devices of public health importance, in particular.

[1] For the purpose of this SOP, the OIR Chief Medical Officer for IVDs or Radiological Health will serve as the OIR Clinical Trials Director.

3. Policy

CDRH typically delegates IDE approvability decisions to the review divisions. In some instances, however, lingering unresolved issues stall progress on an IDE. Involvement of the CT Program in selected submissions provides an opportunity for an objective review of outstanding issues affecting an IDE.

CDRH staff is expected to apply this procedure when IDE deficiencies and/or other unresolved issues persist between the Sponsor and review staff despite repeated attempts to resolve them. Reviewers and managers may also choose to involve the CT Program to help address and resolve specific challenges related to IDE review, even when outside the scope of this SOP.

4. Scope

This SOP applies to any original IDE, new study supplement, or expansion of an existing study, for which a decision other than full approval is made. This includes disapprovals (DSAP) and approvals with conditions (APCN).

4.1. This SOP does not apply to:

4.1.1. Pre-submission (pre-IDE) interactions; or

4.1.2. Formal internal disagreements among CDRH staff which are handled via the existing **SOP for Resolution of Internal Differences of Opinion in Regulatory Decision-Making.**

5. Roles, Responsibilities and Procedures

The CT Program intends to notify the lead reviewer when an IDE subject to this SOP is identified. For sections 5.3 and 5.4, this notification will also provide the name of the CT Program representative assigned to interact with the division for that IDE.

5.1. Sponsor Teleconference

5.1.1. CDRH review staff should offer sponsors a teleconference to occur within 10 business days following any IDE DSAP decision or any second-round or subsequent APCN decision. The purpose of the teleconference is to clarify CDRH's reasons for IDE DSAP or APCN, but not to review additional information submitted by the Sponsor in response to identified deficiencies or discuss issues unrelated to the deficiencies listed in the letter. If a sponsor wishes to meet but cannot meet during the time(s) proposed by the review team, the meeting should be scheduled as soon as is reasonably possible. The review staff is responsible for documenting the purpose and content of the teleconference in the administrative record consistent with existing CDRH policy.

5.2. First Round IDE DSAP and APCN Decisions

5.2.1. Following the issuance of a first round DSAP or APCN decision, the CT Program may, at their discretion, review the decision letter and supporting documentation. Based on this review, if the CT Program wishes to discuss the decision, they should contact the lead reviewer and branch chief within 7 calendar days of the issuance of the IDE letter and schedule a meeting with the appropriate team members and managers. If a sponsor teleconference is scheduled but has not yet occurred, the CT Program may choose to participate. If during this 7-day period, the CT Program either reviews the decision and concurs or decides to not review the decision, they will inform the lead reviewer and branch chief of this determination.

5.3. Second Round (and subsequent) IDE DSAP and APCN Decisions

5.3.1. CDRH review staff should offer sponsors a teleconference (see 5.1.1) and should include the CT Program representative in the 10-day IDE DSAP or APCN teleconference.

5.3.2. The CT Program representative will schedule and facilitate an internal meeting with the review team and relevant Branch and Division management to discuss the IDE and the remaining outstanding issues. This meeting should be conducted prior to the DSAP or APCN teleconference with the sponsor. If the CT Program representative reviews the administrative record and determines an internal meeting is unnecessary, he/she may cancel it at their discretion.

5.4. Third Round (and subsequent) IDE Submissions in Response to DSAP and APCN Decisions

5.4.1. During the third round (and subsequent) IDE submission reviews, consultants are expected to work interactively with the review team throughout the review cycle, although the written review is not due until 14 calendar days from issuance of the consult request.

5.4.2. At least 5 days prior to issuance of a 3rd round (or subsequent) decision letter to the sponsor, the lead reviewer will email the CT Program representative notifying them of the Division decision and providing the draft decision letter and review documents. If necessary due to time limitations, division management may request that the CT Program representative review the documents concurrently with division management, after branch level review and concurrence. The e-mail should have "IDE [ROUND #] ROUND [DECISION] – [file number]" in the subject line.

5.4.3. At their discretion, the CT Program representative may request a meeting with the review team prior to issuance of the letter.

5.5. Documentation and Resolution of IDE Application-Specific Issues

5.5.1. If the CT Program representative and the Division are able to identify a mutually agreeable path forward, then the review Division staff is responsible for documenting the decision and the rationale in the administrative file.

5.5.2. If the CT Program representative and the Division are unable to identify a mutually agreeable path forward, then the issue should be brought to the CT Director for his/her consideration. If discussion with the CT Director leads to the development of a mutually agreeable path forward, then the review Division staff is responsible for documenting the decision and the rationale in the administrative file.

5.5.3. If a mutually agreeable path forward is not reached per 5.5.2, the CT Director will render a decision on behalf of the Office and will summarize in writing his/her decision, including the interactions with the review team, Division management, and CT Program representative as well as the identified next steps and provide a written memo to be included in the administrative file.

5.5.4. If a decision is made to modify the deficiencies, study design considerations, or approval status for an already issued letter, the Division will prepare a corrected IDE letter. The corrected IDE letter should reference the original letter and the sponsor should be contacted in advance of issuance of the corrected letter to explain what changes have been made and the reason for the changes.

5.5.5. Based on the CT Director's decision, the Division may invoke the "CDRH SOP for Resolution of Internal Differences of Opinion in Regulatory Decision-Making" if they wish to do so.

5.6. Appeals

5.6.1. The CT Director is the Office-level appeal authority for requests for supervisory review of IDE decisions under 21 CFR 10.75. If , prior to the appeal, the CT Director has been directly involved in the IDE decision, then the appeal will be elevated to the office of the CDRH Center Director.

6. Change Control Table

VERSION #	REASON FOR CHANGE	REVISION DATE	EFFECTIVE DATE	APPROVING OFFICIAL (NAME/TITLE)
1.0	Original	January 23, 2014	March 1, 2014	/s/ William H. Maisel, MD, MPH CDRH Deputy Center Director for Science
2.0	Streamline communication with reviewers and implement CTD review of first round decisions	September 26, 2014	October 1, 2014	Owen Faris, PhD Clinical Trials Director (acting) CDRH
3.0	Clarification of Clinical Trial Program roles and appeal authority for IDE decisions	January 21, 2016	February 1, 2016	Owen Faris, PhD Clinical Trials Director CDRH