

GENERAL INSTRUCTIONS – AMENDMENTS AND SUPPLEMENTS

WHAT IS THE DIFFERENCE BETWEEN AMENDMENT AND SUPPLEMENT?

Amendment - An IDE amendment is any additional submissions to an IDE before approval of the IDE.

Supplement - An IDE supplement is any additional submission to an IDE *after* approval of the IDE.

WHAT KIND OF AMENDMENTS CAN OCCUR?

It is possible that you may need to submit items to your IDE while it is still under initial review. These submissions are technically called ‘amendments’. They can be comprised of anything the agency might still need to fully review your application (additional manufacturing information, CRFs, more details on your investigation plan, missing documentation etc.)

WHAT KIND OF SUPPLEMENTS CAN OCCUR?

You will keep your IDE ‘current’ by submitting regular supplements to your application when things change or you have information to update. You will need approval for some of these changes ahead of time. Some examples are given below:

Changes in Investigational Plan – most of the time, changes that are made in the Investigational Plan, need to be pre-approved by FDA. Examples of these changes are:

1. **Changes in the Investigational Plan or Protocol**
 - Affecting the validity of data/information,
 - Patient risk to benefit relationship,
 - Scientific soundness of investigational plan,
 - Right, safety or welfare of subjects.
2. **Developmental Changes** that present a significant change in design or basic principle of operation

Exceptions to the pre-approval requirements are:

1. **Changes Effected for Emergency Use**-are considered to be changes in the investigational plan to protect the life or well-being of the subject in the case of emergency. However, these changes must be reported to the FDA **within 5-working days**.
2. **Non-significant changes in design or manufacturing** - those changes should also be reported to the FDA within **5-working days**.
3. **Other** minor changes that could be reported as a part of Progress Report

IRB approval of new facility-a Sponsor-Investigator shall include all documentation about the new facility and the IRB approval if it was not included in the initial IDE application.

WHERE CAN I GET MORE INFORMATION ON DOES MY CHANGE REQUIRES PRIOR APPROVAL?

- Guidance on Changes or Modifications During the Device Trial
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082145.htm>

WHERE DO I SEND SUPPLEMENTS AND/OR AMENDMENTS?

For a CDRH Submission:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850
ATTN: [Insert Appropriate Name]

For a CDER Submission:

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266
ATTN: [Insert Appropriate Name]

For a CBER Submission:

Food and Drug Administration
Center for Biologics Evaluation and Research
HFM-99, 200N
1401 Rockville Pike
Rockville, MD 20852-1448
ATTN: [Insert Appropriate Name]

TO WHOM DO I ADDRESS SUPPLEMENTS AND/OR AMENDMENTS?

All IND Amendments/Supplements are sent to the appropriate central document room (CBER, CDER or CDRH) and addressed to the person identified by the FDA in your initial “notification letter” as your ‘project manager’.

WHAT/WHEN CAN I EXPECT TO HEAR BACK FROM FDA REGARDING MY SUBMISSION?

If you requested a pre-approval of certain modification in your Clinical trial, FDA will review these submissions within 30 days and issue an approval, conditional approval, or disapproval letter.

WHERE CAN I GET MORE INFORMATION?

- 21 CFR 812.35, Supplemental Applications
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.35>
- “Device Advice” on IDE Reports at the FDA website:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046717.htm>
- “Device Advice” on IDE Reports at the FDA website:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046706.htm#addfor>