FDLI’s Introduction to Medical Device Law and Regulation: Understanding How FDA Regulates the Medical Device Industry

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Investigational Device Exemptions (IDE), Clinical Trial Issues, and Medical Device Reimbursement

presented by

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I. Investigational Device Exemptions (IDE) – FDCA § 520(G); 21 C.F.R. Part 812

A. Overview

1. Permits Distribution Of Medical Devices For Investigational Purposes.

2. Exempts Device From Misbranding, Adulteration, 510(k), PMA, Registration, Listing, And GMP Provisions.

B. Investigations With The Following Devices Are Exempt From IDE Regulation

1. Diagnostic Devices Provided That:
   a) Complies With IVD Labeling Requirements (21 C.F.R. § 809.10);
   b) Noninvasive;
   c) No Invasive Sampling That Presents Significant Risk (Simple Venipuncture And Use Of Surplus Samples Are Non-Invasive);
   d) Does Not Introduce Energy Into The Body; And
   e) Not Used For Diagnosis Without Confirmation By Another Medically Established Product Or Procedure. 21 C.F.R. § 812.2(c)(3)


3. Veterinary Use Devices.


C. Abbreviated Requirements For Non-Significant Risk Devices If:

1. Labeled As Investigational Device.


3. Obtain Informed Consent.

4. Follow a Written Protocol

5. Comply With All Monitoring Requirements (See 21 C.F.R. § 46 (1992)).
6. Comply With All Record Keeping And Reporting.
7. Ensure Investigators Comply With Reporting.

D. An IDE Application Must Be Filed If Device Represents A Significant Risk.

For Guidance In Determining Whether A Study Is A “Significant Risk” Study, see “Significant Risk And Nonsignificant Risk Medical Device Studies” [Exhibit 1]

E. Submitting An IDE Application (If Significant Risk Device).

The IDE Application Must Include (21 C.F.R. § 812.20):

1. Sponsor’s Name And Address.
3. Description Of Manufacturing Practices And Quality Controls.
4. Investigator Agreements.
5. Information On IRB.
6. Patient Informed Consent Form And Information.
7. Copies Of All Labeling.
8. Environmental Analysis.
9. Amount To Be Charged For Device And Explanation Why That Is Not Commercialization.


F. Starting IDE Study

1. If non-significant risk device, immediately upon IRB approval.
2. If significant risk device, thirty days after FDA receives application unless FDA disapproves the IDE. FDA often asks questions which delay the start beyond 30 days.
3. Under FDAMA, sponsors of Class III devices or any Implantable Device may meet with FDA to discuss investigational plan prior to submission of an IDE (FDCA § 520(g)(7)).

G. Changes to an Investigational Plan, See Guidance: “Changes and Modifications During the Conduct of a Clinical Investigation” (2001) [Exhibit 3].

1. IDE Supplement.
2. Notice to FDA.
3. IDE Annual Report

H. Sponsor and Investigator Responsibilities

1. General Monitoring, Reporting And Recordkeeping Requirements.
2. Compliance With Investigational Plan

II. ACCESS TO UNAPPROVED DEVICES

A. Investigational Devices

2. Investigators Who Repeatedly Or Deliberately Fail To Comply With Applicable Requirements Or Submits False Information To The Sponsor Or FDA “Disqualified.”
   a) Not Entitled To Receive Investigational Devices.
   b) FDA Will Examine Applications Which Contain Data From Disqualified Investigators.
   c) May Result In FDA Withdrawing Approval Or Rescinding Clearance.

B. Prohibitions Against Promotion (21 C.F.R. § 812.7)
1. No Promotion or Test Marketing.
2. No Charging Subjects or Investigators a Price Larger Than Necessary to Recover Costs of the Manufacture, Research, Development and Handling.
3. No Unduly Prolonging Investigation.
4. No “Safe” or “Effective” Claims.

III. ETHICAL ISSUES IN CLINICAL TRIALS
   A. Institutional Review Boards (IRBs) Responsibilities.
   B. Informed Consent.
   C. Inspections/Bioresearch Monitoring Program. See FDA Consumer article, “Human Research Reinstated at Johns Hopkins, with Conditions” [Exhibit 6].
   D. Other Issues.
      1. Data Tampering.
      2. Integrity of Electronic Records.
      3. Improper Incentives to Enrollment.
      4. IRB Shopping.

IV. MEDICAL REIMBURSEMENT FOR INVESTIGATIONAL DEVICES
   A. Medicare Coverage for IDE Category B Devices and “Medically Necessary” Related Services.
      1. FDA/HCFA Interagency Agreement (1995) [Exhibit 7].
      2. CMS Regulations at 42 C.F.R. §§ 405.201-405.215 [Exhibit 8].
   B. Medicare Coverage for “Routine Costs” Associated with Qualified Clinical Trials