

CHAPTER 48 - BIORESEARCH MONITORING - DRUGS, DEVICES, BIOLOGICS, and FOODS

SUBJECT: INSTITUTIONAL REVIEW BOARD	IMPLEMENTATION DATE 10/01/94
	COMPLETION DATE 09/30/97
DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
45Z Foods 46Z 57Z Biologics 99Z 60Z Drugs 61Z 73Z Devices 74Z	09809 *41809 (therapeutics) *42809 (blood) *45809 (vaccines) 48809 83809

Field Reporting Requirements

All establishment inspection reports (EIR's), complete with attachments, exhibits, and any related correspondence are to be submitted in a timely fashion to the assigning Center.

If an EIR contains serious findings raising the possibility of one or more violations of the FD&C Act or other federal statutes, a copy of the EIR should be forwarded to the District Compliance Branch at the time it is sent to the Center.

Current Change

Vintage Documents from Clinical Device Group

Is this the document you are looking for? Just email us [here](#) to obtain the entire copy of the FDA Bioresearch Monitoring's October 1994 "Bioresearch Monitoring Compliance Guide for IRBs 7348-809," free and with our compliments.

Best regards,
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President, Clinical Device Group Inc

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