

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

SUBJECT:  INSTITUTIONAL REVIEW BOARD	IMPLEMENTATION DATE  10/01/94
	COMPLETION DATE  09/30/97
<b>DATA REPORTING</b>	
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,  
Nancy J Stark, PhD  
President, Clinical Device Group Inc

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