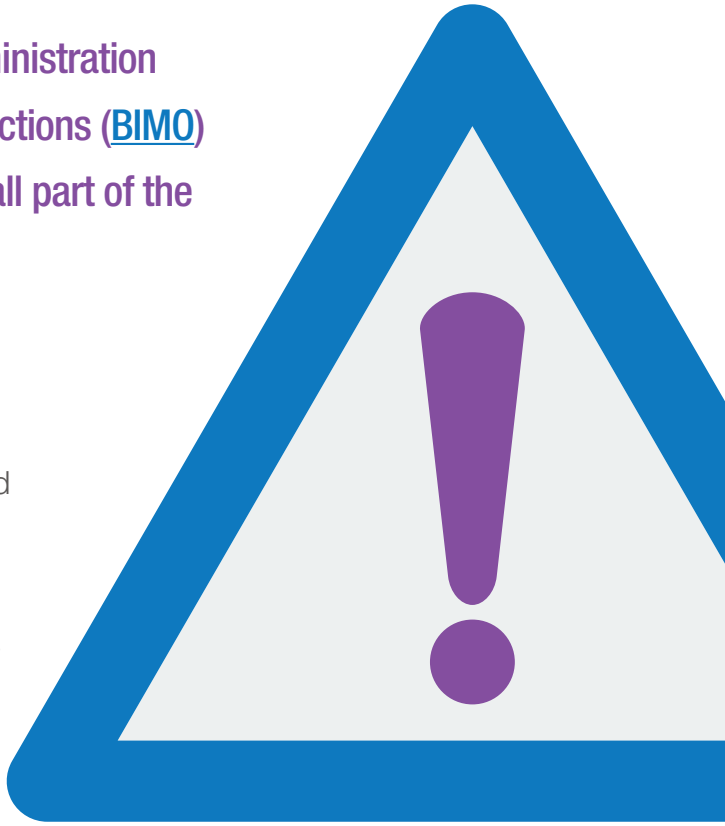
imarc
WE'LL EARN YOUR APPROVAL.

# TOP 5 REASONS AN FDA WARNING LETTER IS ISSUED TO AN IRB

**During the 2016 fiscal year the Food and Drug Administration (FDA) completed 124 Bioresearch Monitoring Inspections (BIMO) of Institutional Review Boards (IRB); this was a small part of the total 1055 BIMO inspections completed last year.**



Of these inspections, there were three warning letters issued. At IMARC Research, Inc., we review the warning letters issued to Clinical Investigators on a yearly basis and recently put together a whitepaper on the 2016 findings. This year, we also reviewed the warning letters issued to IRBs, with the intention of understanding the expectations of IRBs set forth by the FDA.

## The common IRB deficiencies summarized by the FDA for Fiscal Year 2016 include the following:

- Inadequate initial and/or continuing review
- Inadequate written procedures
- Inadequate meeting minutes, membership rosters
- Quorum issues
- Prompt reporting of non-compliance, suspension/termination
- Subpart D issues
- Lack of or incorrect SR/NSR determination

# Digging deeper into the warning letters issued, IMARC noted the following deficiencies cited, listed below from least to most frequent:

## NUMBER FIVE

Failure to conduct continuing review of research at intervals of not less than once per year [21 CFR 56.109(f)].

- Example: Completing continuing review greater than one year after previous study review.

## NUMBER FOUR

Failure to review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas [21 CFR 56.1089(c)].

- Example: Reviewed FDA-regulated research at meetings where a majority of the IRB members were not present.

## NUMBER THREE

Failure to notify investigators and the institution in writing of its decision to approve or disapprove proposed research activities or of modifications required to secure IRB approval of the research activity [21 CFR 56.109(e)].

- Example: Failure to notify the investigator in writing of approval of randomization change.

## NUMBER TWO

Failure to prepare, maintain, and follow required written procedures governing the functions and operations of the IRB [21 CFR 56.108(a), 21 CFR 56.108(b), and 21 CFR 56.115(a)(6)].

- Example: Failure to maintain written procedures for conducting the IRB's initial and continuing review of research and for reporting the IRB's findings and actions to the investigator and the institution.

## NUMBER ONE

Failure to prepare and maintain adequate documentation of IRB activities, including minutes of IRB meetings [21 CFR 56.115(a)].

- Example: Failure to maintain IRB meeting minutes including documentation of vote counts and membership lists.
- Example: Failure to document the vote on IRB actions including the number of members voting for, against, and abstaining.

These findings reiterate the importance for IRBs to maintain proper documentation. IRBs, investigational sites, and monitors need to continue to work together to ensure that the study protocols, site's standard operating procedures, and federal regulations are being followed so that the rights, safety, and well-being of patients are protected.

imarc

WE'LL EARN YOUR APPROVAL.

imarcresearch.com • info@imarcresearch.com

Reference: BIMO Metrics