FY 2023 IRB FDA 483 OBSERVATION TRENDS

Purpose

Broadly written regulations do not always convey the specific details of the observed violation(s).

FDA 483 citations issued during this fiscal year were reviewed and sub-categorized into more granular themes in order to identify trends.

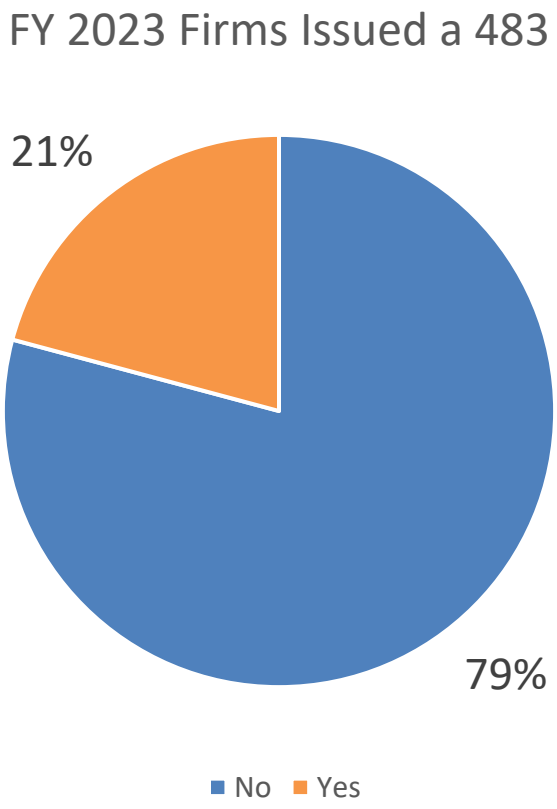
These data slides are the result of the sub-categorization efforts.

Acronyms

IRB (Institutional Review Board)

FDA (Food and Drug Administration)

Number of Inspections – 72
FDA 483 Issued – 15
No FDA 483 Issued - 57



Themes Identified in FY 2023 IRB Data

IRB Communications/Meeting Minutes Deficiencies
(56.110(c), 56.115(a)(2) 56.109(e), 56.113)

No or Not Following Written Procedures
(56.108(a)(1),56.108(b)(1), 56.108(b)(2), 56.108(b)(3), 56.110(b)(1), 56.110(b)(2)), 56.110(c)

IRB Membership Deficiencies (56.107(e), 56.108(c), 56.115(a)(5))

Operational Deficiencies

Details for Themes

IRB Communications/Meeting Minutes Deficiencies

- Investigator not notified in writing for approval or termination of research approval
- Meeting minutes don't document vote counts at all or incorrectly
- Meeting minutes don't document all actions
- No meeting minutes were available for convened meetings
- Meeting minutes don't accurately list members present/alternate voters
- IRB has not notified the Institution in writing of IRB actions
- Termination of approval for research did not include a statement of the reasons for the IRB's action

Details for Themes

No or Not Following Written Procedures

- IRB used an expedited review procedure to approve materials for studies that were more than minor changes to research or did not notify the IRB of expedited approvals
- IRB has no or did not follow written procedures for ensuring prompt reporting to the FDA or institutional officials of any unanticipated problems involving risks to human subjects or others
- IRB has no or did not follow written procedures for reporting any instance of serious or continuing noncompliance with 21 CFR Part 56 or the requirements or determinations of the IRB to FDA
- IRB has no or did not follow written procedures for reporting suspension or termination of IRB approval to FDA
- IRB has no or did not follow written procedures for conducting its initial and continuing review of research

Details for Themes

IRB Meeting Attendance/Membership List Deficiencies

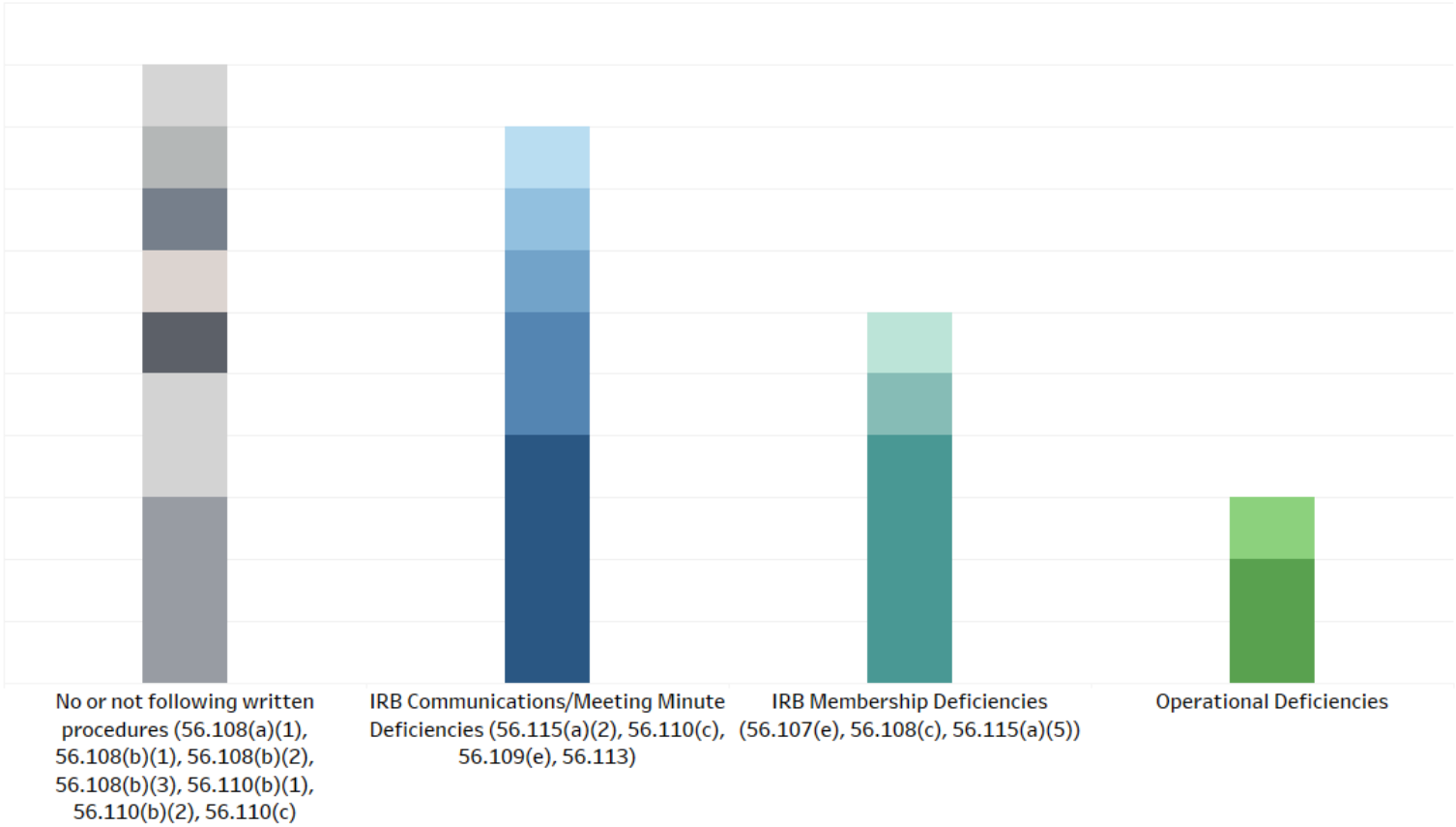
- Non-scientific member not present at meeting
- Majority of members not present at meeting
- Complete membership list not maintained for three years
- An IRB member was allowed to participate in the IRB's continuing review of a project in which the member had a conflicting interest

Details for Themes

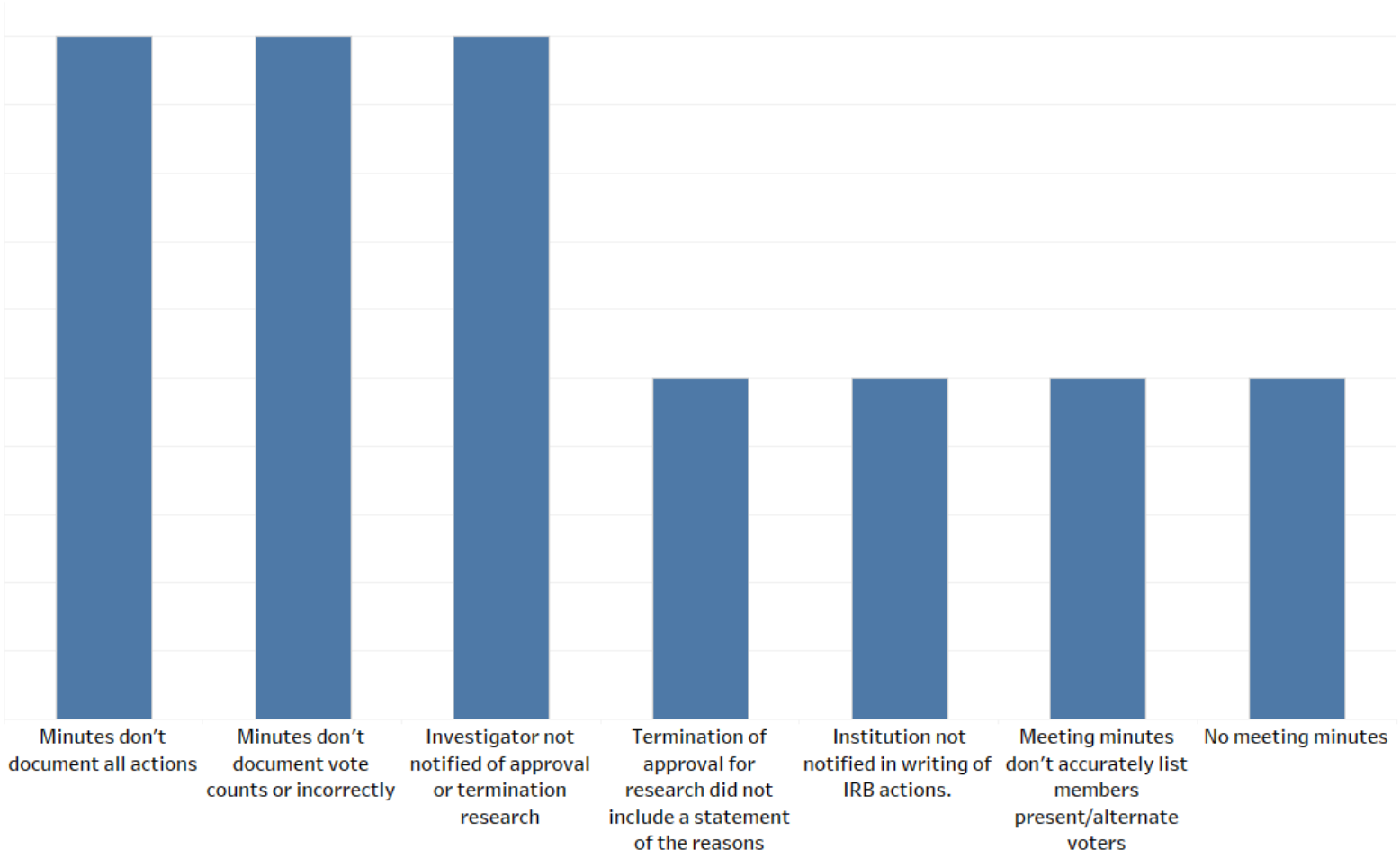
Operational Deficiencies

- IRB does not conduct continuing review of research not less than once per year
- Factors for approval; research involving children-IRB approved a study involving children without finding and documenting that the risk was justified by the anticipated benefit to the subjects and the relation of the anticipated benefit to the risk was at least as favorable to the subjects as that presented by available alternative approaches

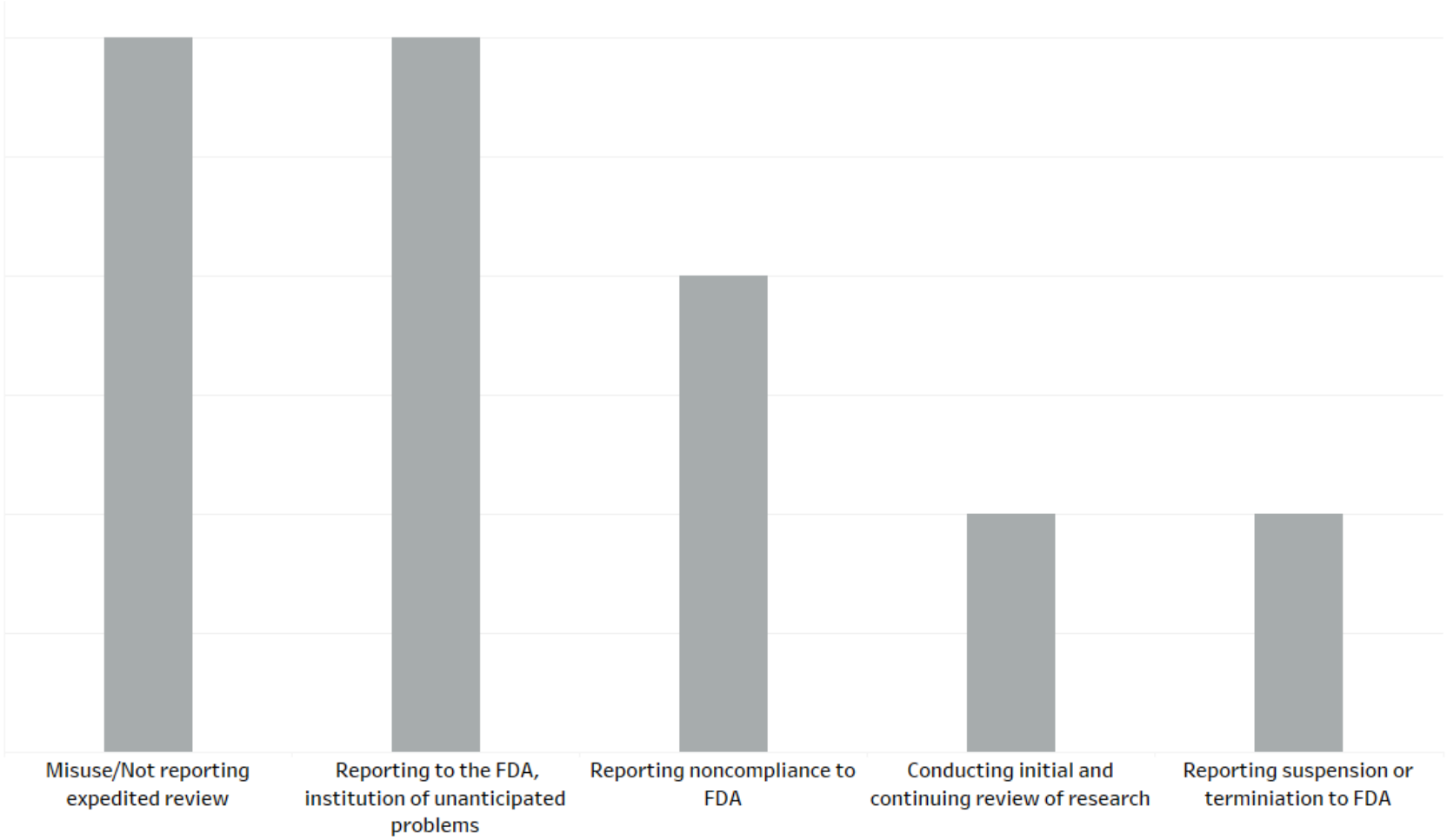
FY 2023 Most Common IRB Short Cites by Themes



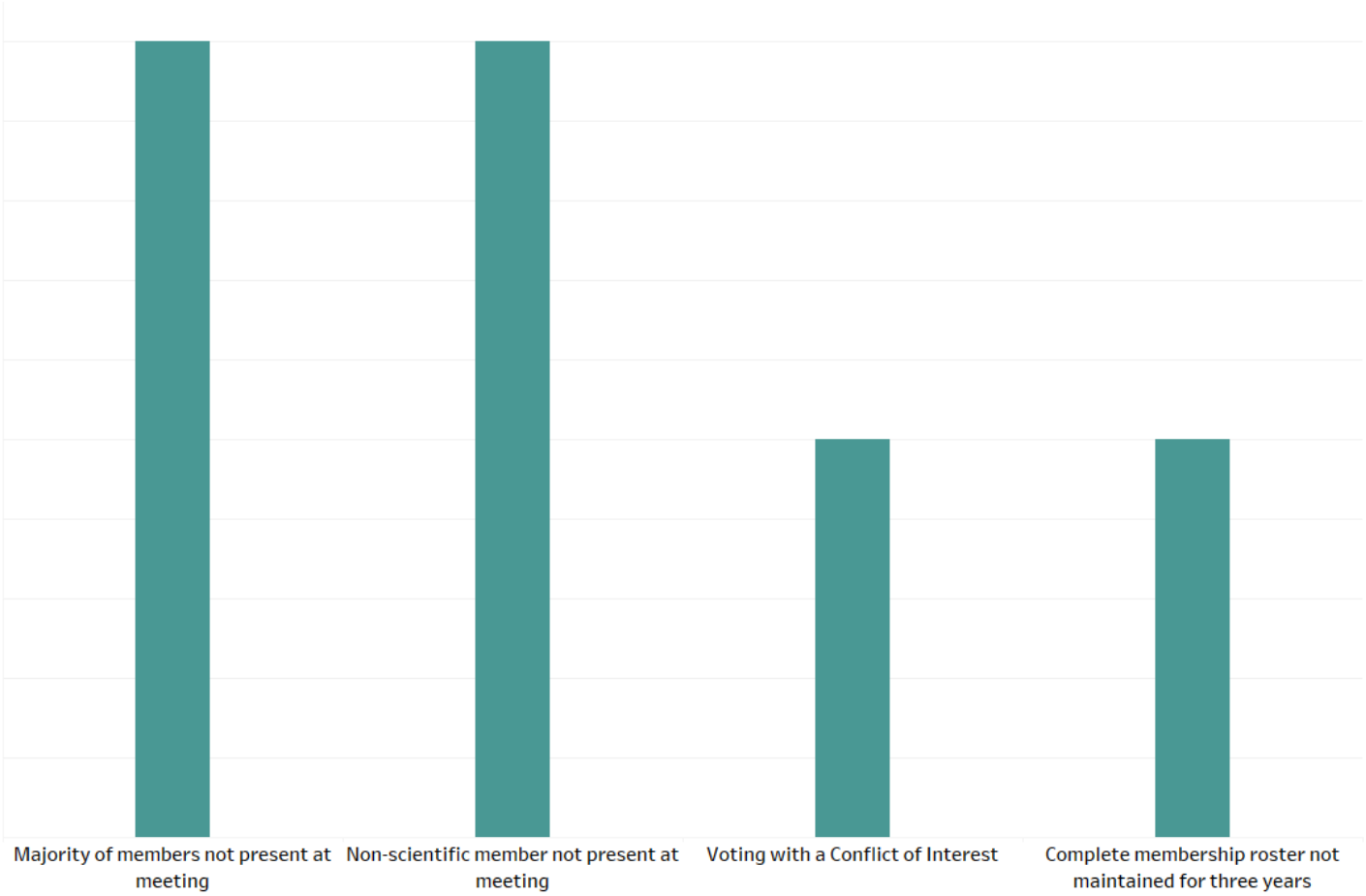
IRB Communications/Meeting Minute Deficiencies Details



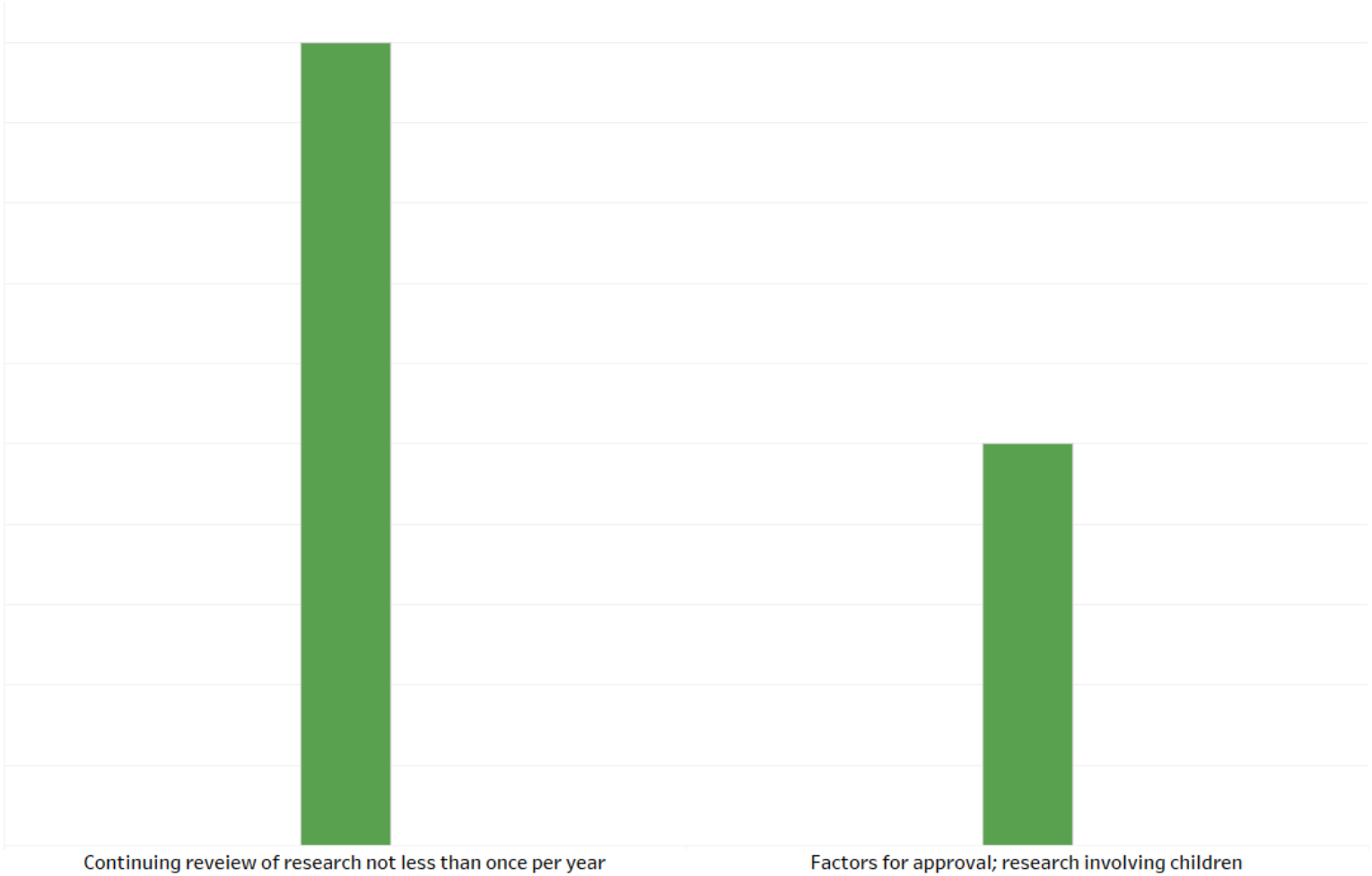
No or Not Following Written Procedures Deficiencies Details



IRB Membership Deficiencies Details



IRB Operational Deficiencies Details

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