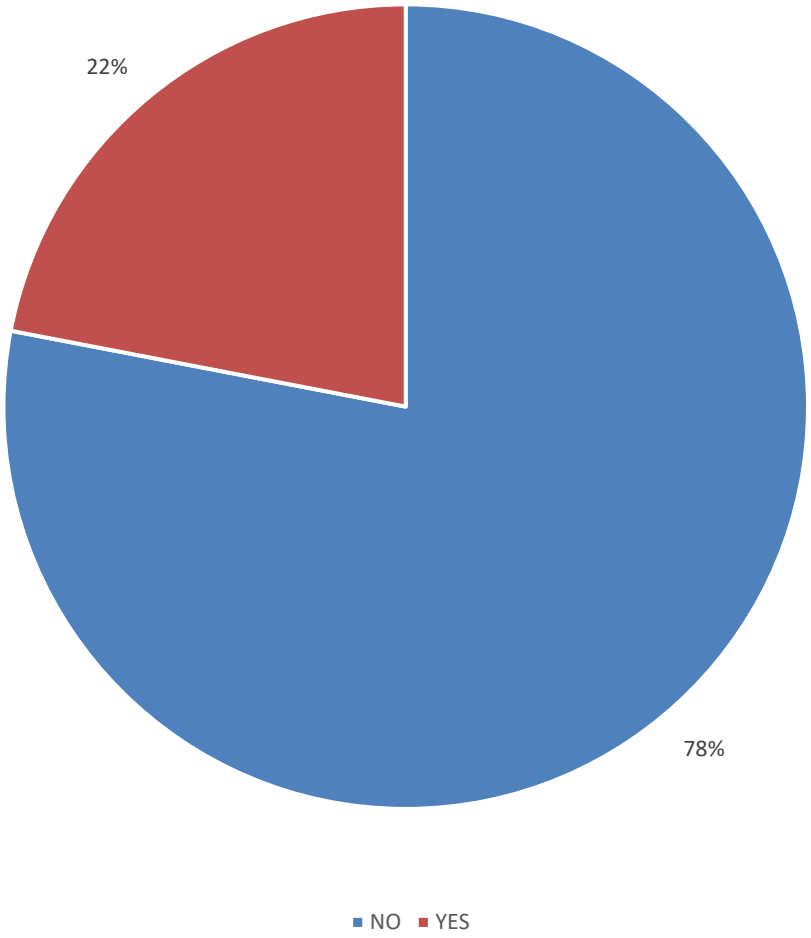
FY 2022 IRB FDA 483 OBSERVATION TRENDS

FY 2022 Institutional Review Boards Issued a 483



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)

CI (Clinical Investigator)

FDA (Food and Drug Administration)

ICF (Informed Consent Form)

Themes Identified in FY 2022 IRB Data

- IRB Communications/Minutes Deficiencies (56.110(c), 56.115(a)(2))
- Not Following/Lack of Written Procedures (56.108(a)(1), 56.108(b)(2), 56.108(b)(3), 56.115(a)(6), 812.66, 56.110(b)(1))
- Maintenance of Records/Correspondence Deficiencies (56.115(a)(3), 56.115(a)(4), 56.115(b))
- IRB Registration Deficiencies (56.106 (c), 56.106(e))
- IRB Roster/Membership Deficiencies (56.107(d), 56.108(c), 56.115(a)(5))
- Informed Consent Deficiencies (50.25 (a)(2), 50.25 (a)(8), 50.25(c))

Details for Themes

IRB Communications/Minutes Deficiencies

- No procedure for keeping IRB membership notified of materials approved using expedited review
- No documentation in minutes of discussion of controverted issues or resolution
- Minutes don't document vote counts at all or does so incorrectly
- Minutes don't document all review actions
- Minutes don't accurately list count of members present/alternate voters

Details for Themes

Not Following/Lack of Written Procedures

- Firm did not follow written procedures
- IRB has no written procedures for reporting noncompliance to the FDA
- IRB has no written procedures for reporting suspension or termination specifically to the FDA
- IRB used an expedited review procedure to approve materials for studies that were more than minimal risk to subjects
- Written procedures were not established
- No device risk determination of significant or non-significant risk was performed during the review process

Details for Themes

Maintenance of Records/Correspondence Deficiencies

- No documentation of Continuing Review and conditional approval or documentation of study closure
- Missing correspondence between IRB and clinical investigator
- Missing meeting minutes for approved study
- Missing initial/continuing review materials

Details for Themes

IRB Registration Deficiencies

- IRB registration expired
- IRB didn't revise registration when chairperson changed
- IRB wasn't registered to review new types of studies
- IRB didn’t notify FDA of termination of IRB

Details for Themes

IRB Roster/Membership Deficiencies

- The IRB does not include at least one member who is not otherwise affiliated with the institution, and who is not part of the immediate family of a person who is affiliated with the institution
- Nonscientific member on roster, but not present at meeting
- Quorum not met
- Complete membership roster was not maintained for three years

Details for Themes

Informed Consent Deficiencies

- Informed Consent Form (ICF) stated study has no safety concerns, but product has risks and side effects
- ICF says subjects will complete withdrawal form explaining reasons for withdrawal, while also stating subject can withdraw at any time without giving a reason
- ICF does not contain ClinicalTrials.gov statement

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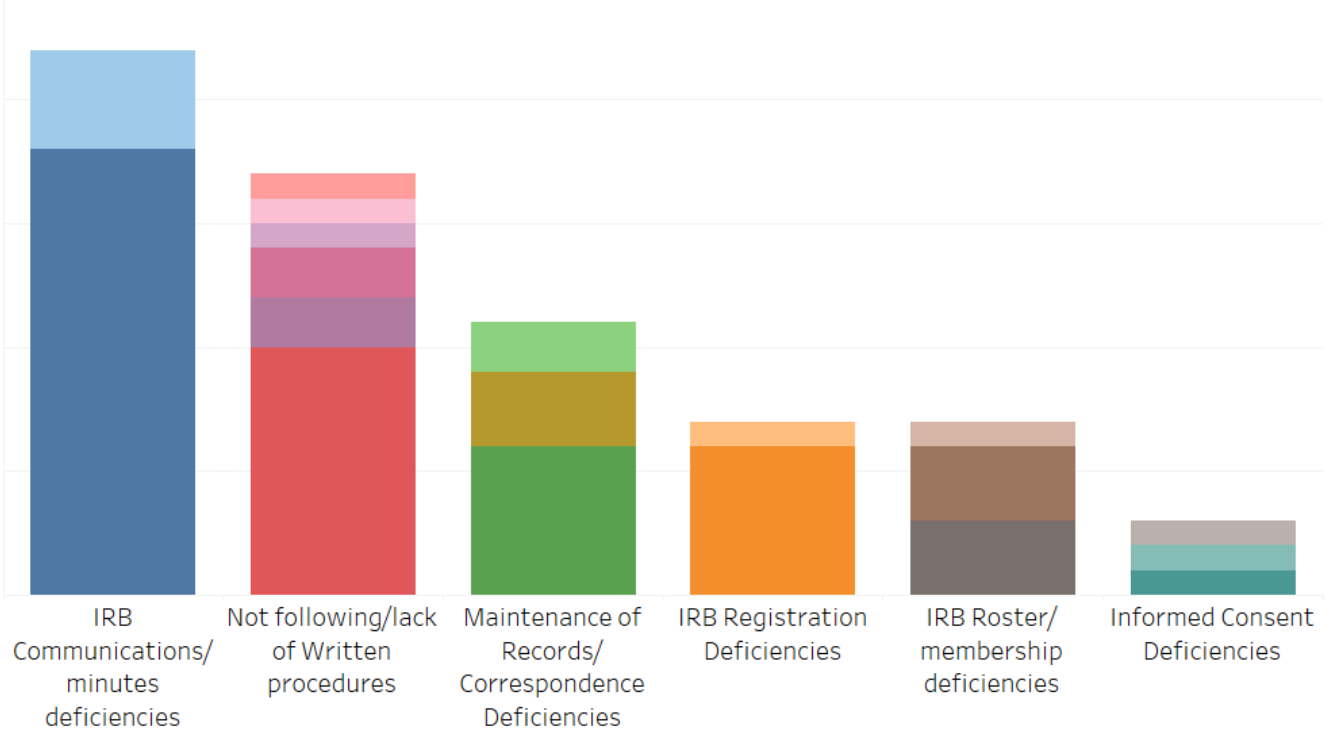
FY 2022 Trends by Reference Numbers



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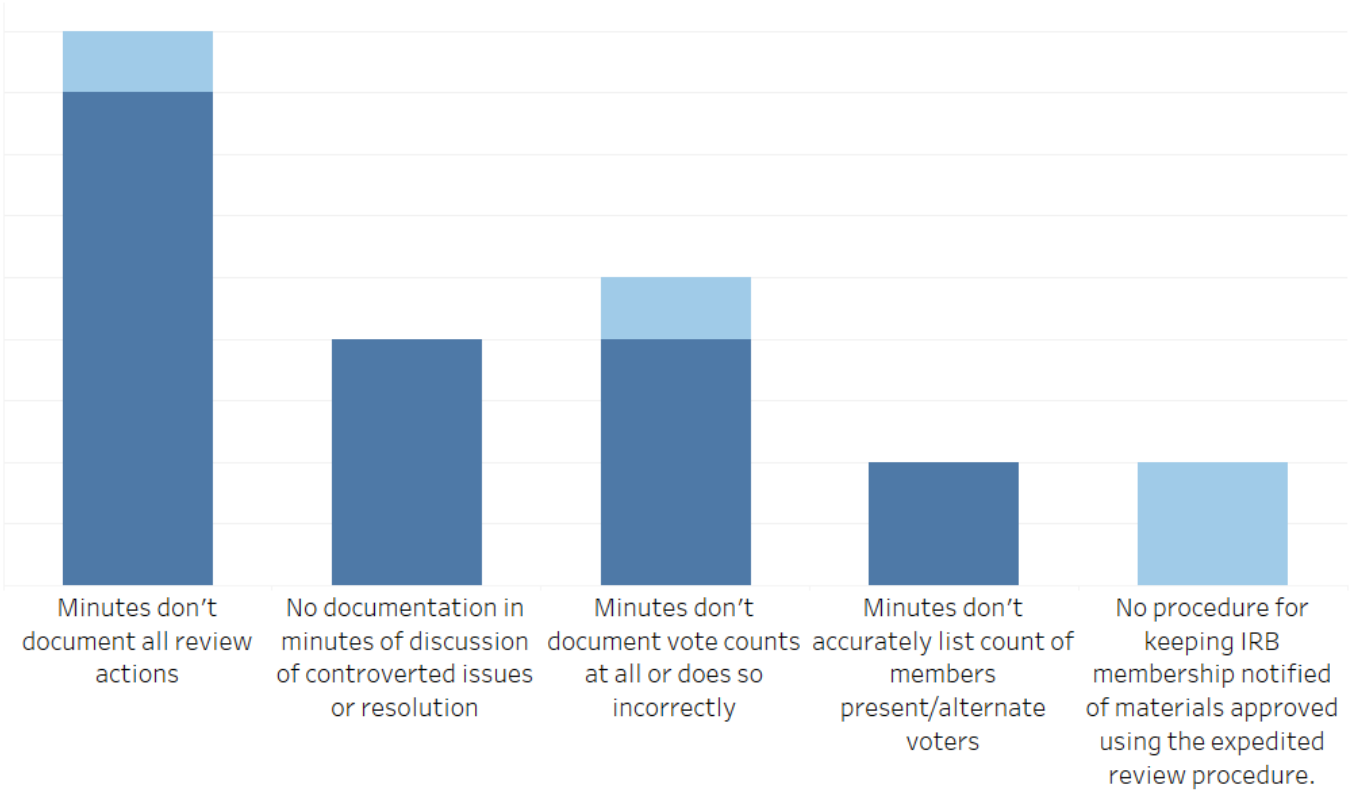
IRB Communications/Minutes Deficiencies Details



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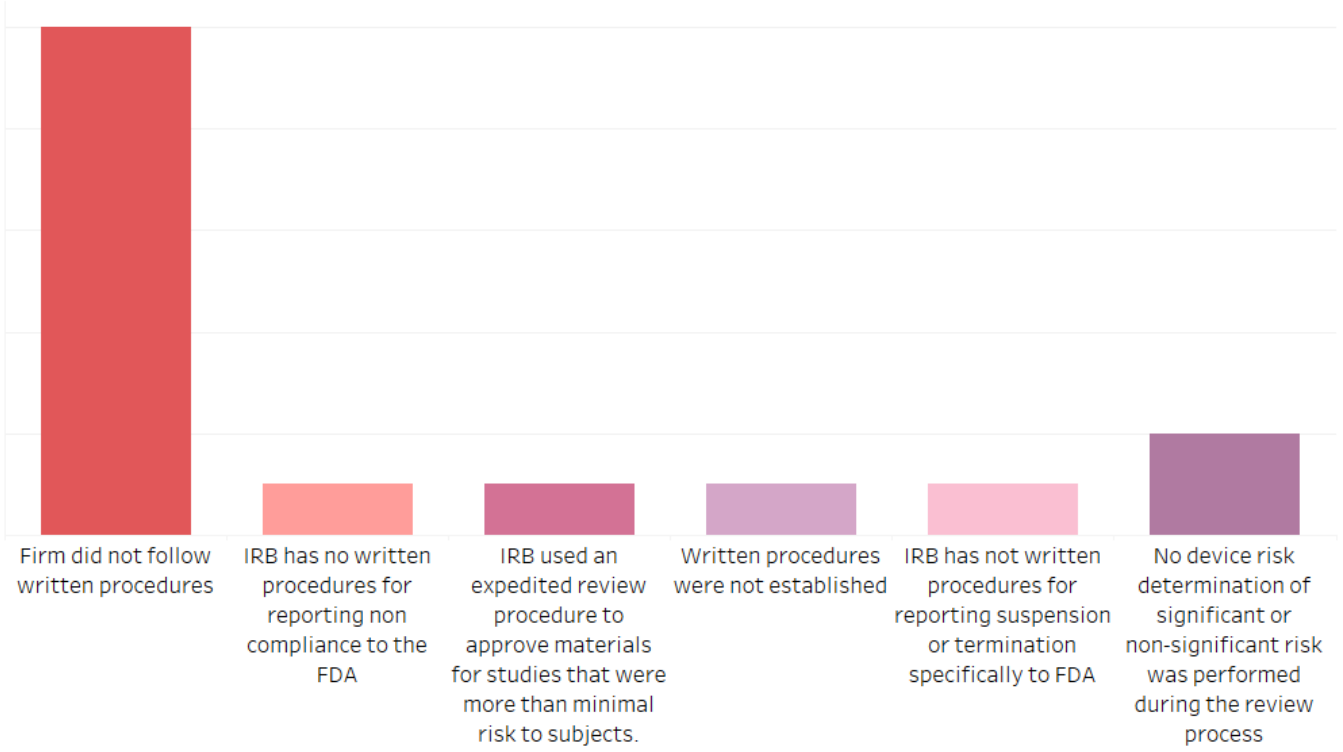
Not Following/Lack of Written Procedures Details



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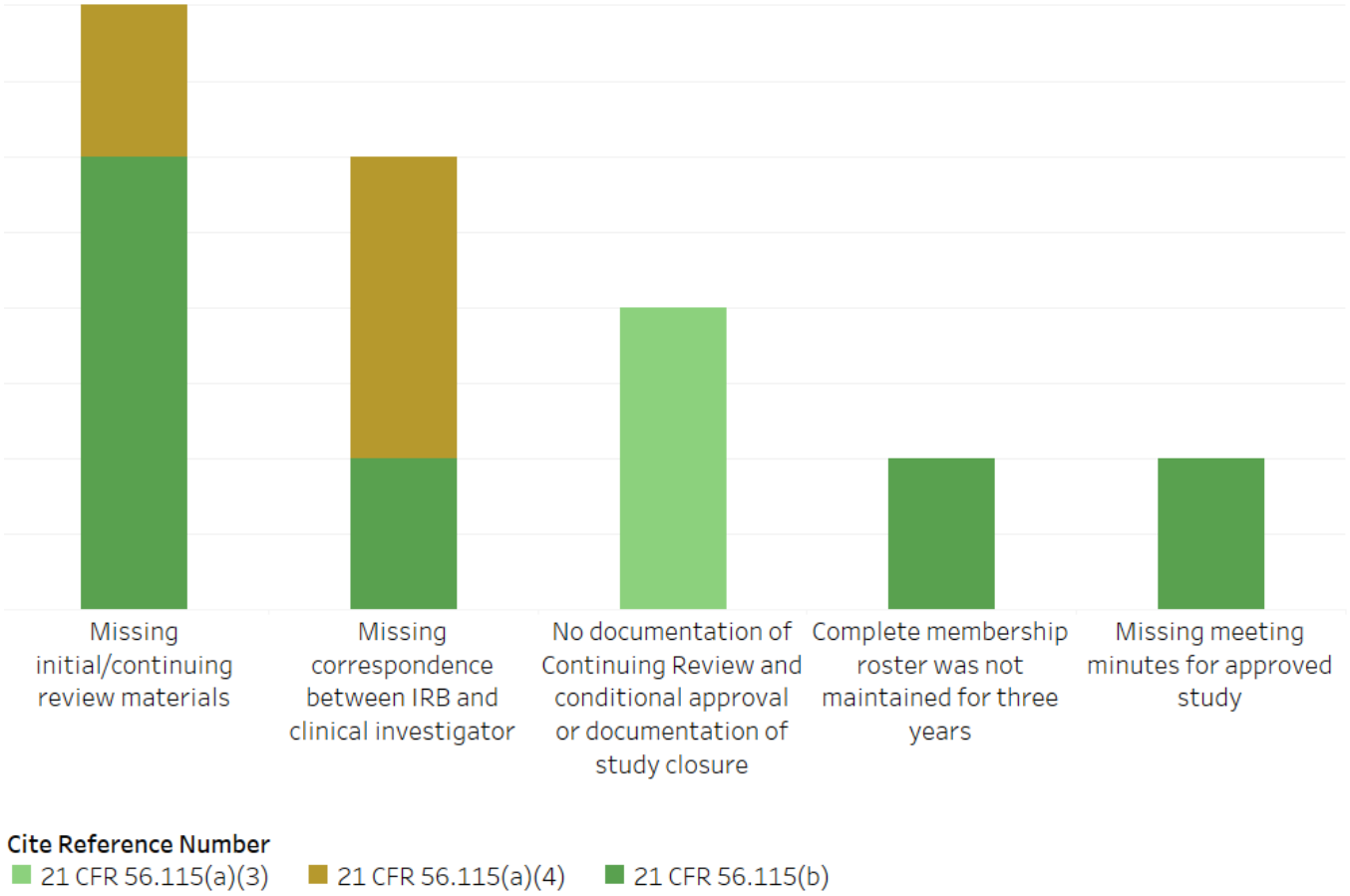
Maintenance of Records/Correspondence Deficiencies Details



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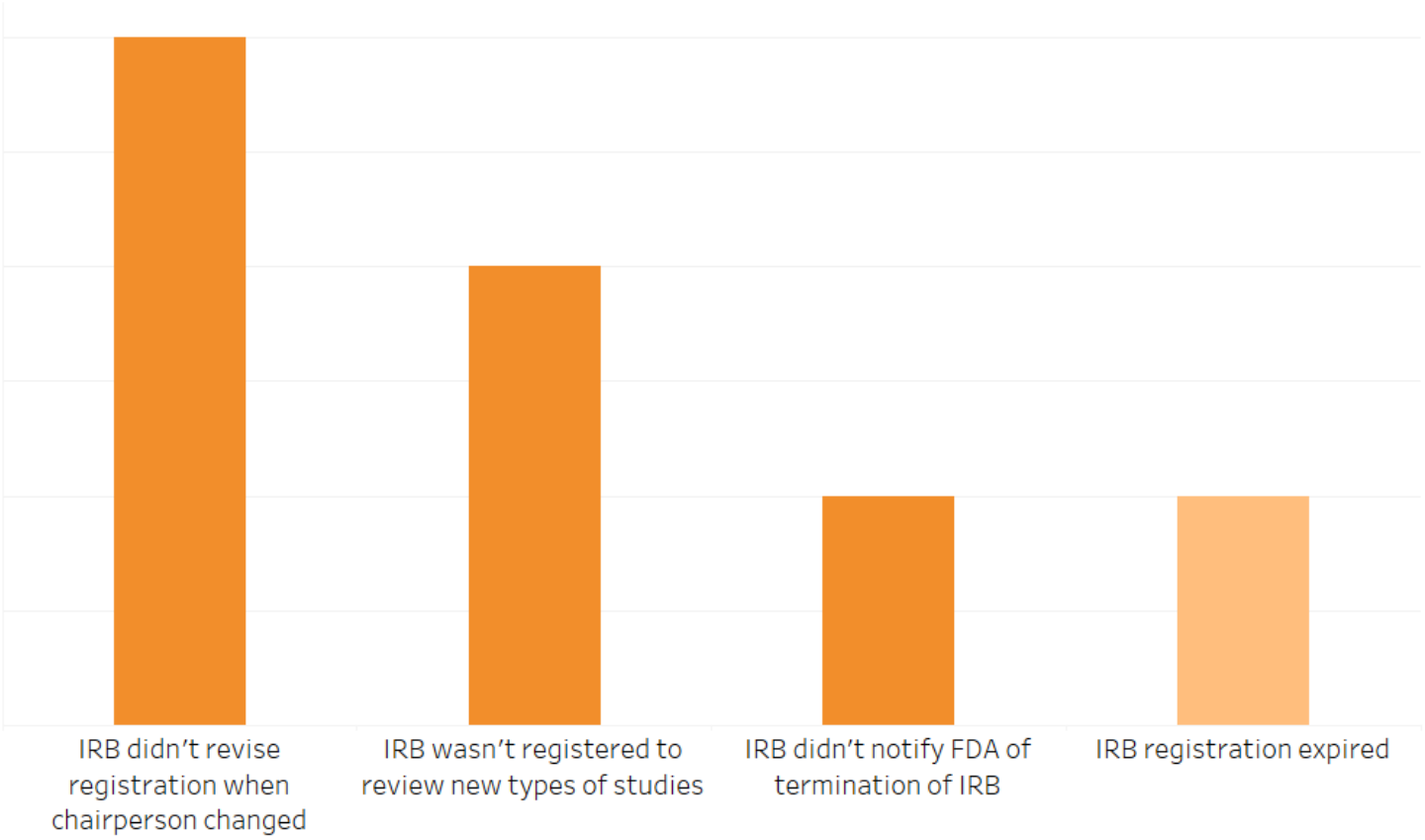
IRB Registration Deficiencies Details



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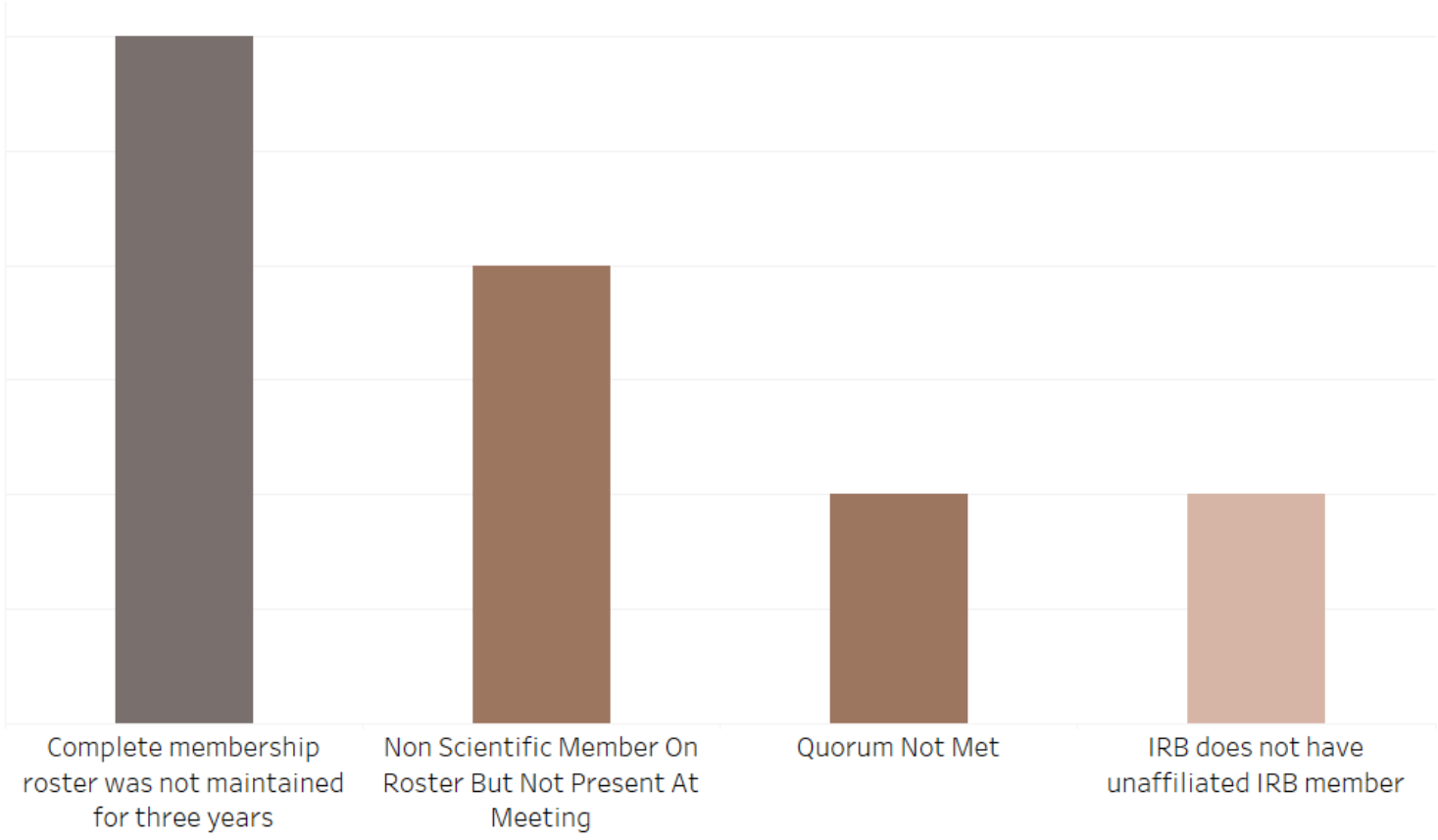
IRB Roster/Membership Deficiencies Details



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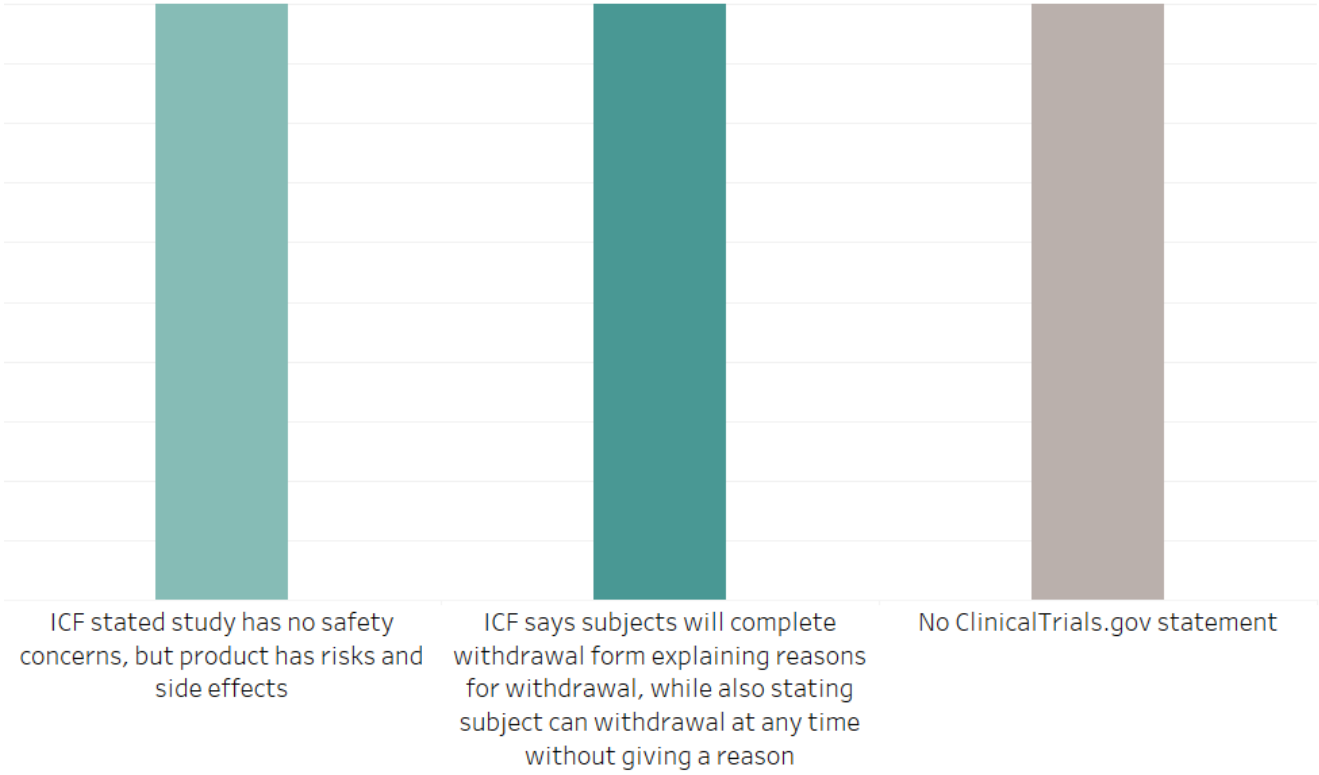
Informed Consent Deficiencies Detail

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