

# **FY 2021 SPONSOR FDA 483 OBSERVATION TRENDS**

## Acronyms

**FDA (Food and Drug Administration)**

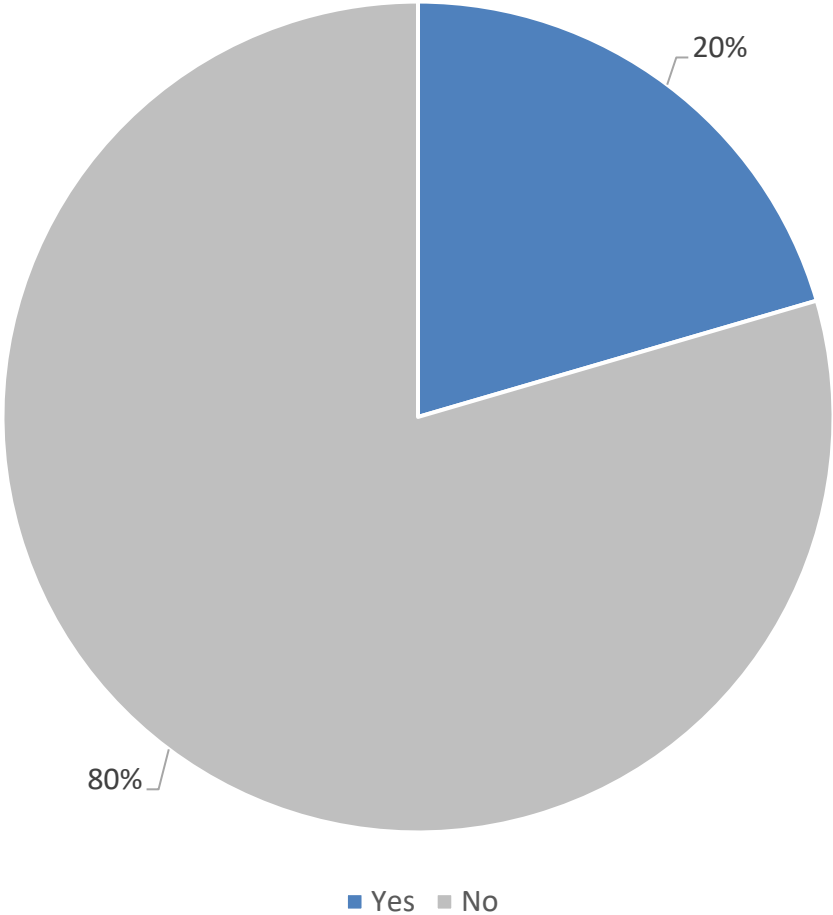
**ICF (Informed Consent Form)**

**IND (Investigational New Drug)**

**IRB (Institutional Review Board)**

**PD (Protocol Deviation)**

### FY 2021 Sponsor Firms Issued a 483



FY 21 data from ORA's Online Reporting Analysis Decision Support System Query, Last updated 8/24/2022

# Trends and Themes Identified in FY 2021 Sponsor Data

Inadequate Monitoring

Failure to Secure Compliance

Inadequate Case Histories

Failure to Submit an IND to FDA

Lack of IRB Approval

Missing ICF Elements

# Details for Themes

## Inadequate Monitoring

- Monitoring plans not followed  
Example: Late analysis of PDs and AEs
- CRO contracts not renewed resulting in no monitoring of sites

## Failure to Secure Compliance

- Ineffective action plans for repeated CI non-compliance
  - Kept CI on study
  - Did not discontinue shipment of study drug to site
- Ineligible subjects enrolled
  - 74 of 181 enrolled (one site)

# Details for Themes

## Inadequate Case Histories

- Documentation of study procedures
  - ICF conducted prior to study procedures
  - Required time schedules
  - Dose times
- Evaluation of adverse events and PDs
- Corrections made w/out documentation of who & when source records were changed

## Failure to Submit an IND to FDA

- INDs not submitted to FDA prior to treating subjects with IP

# Details for Themes

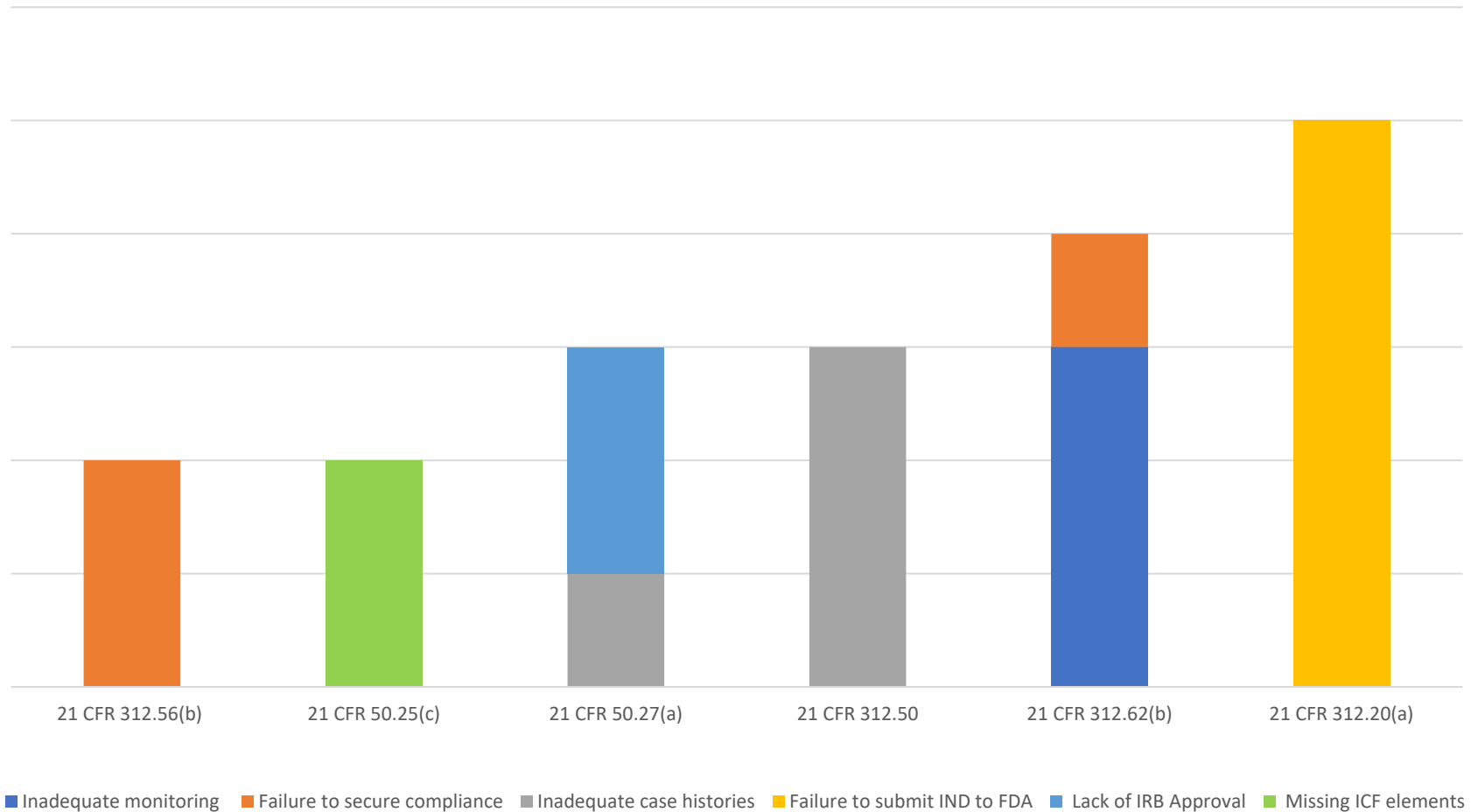
## Lack of IRB Approval

- ICFs not approved by IRB prior to use
- Study initiated without IRB approval

## Missing ICF Elements

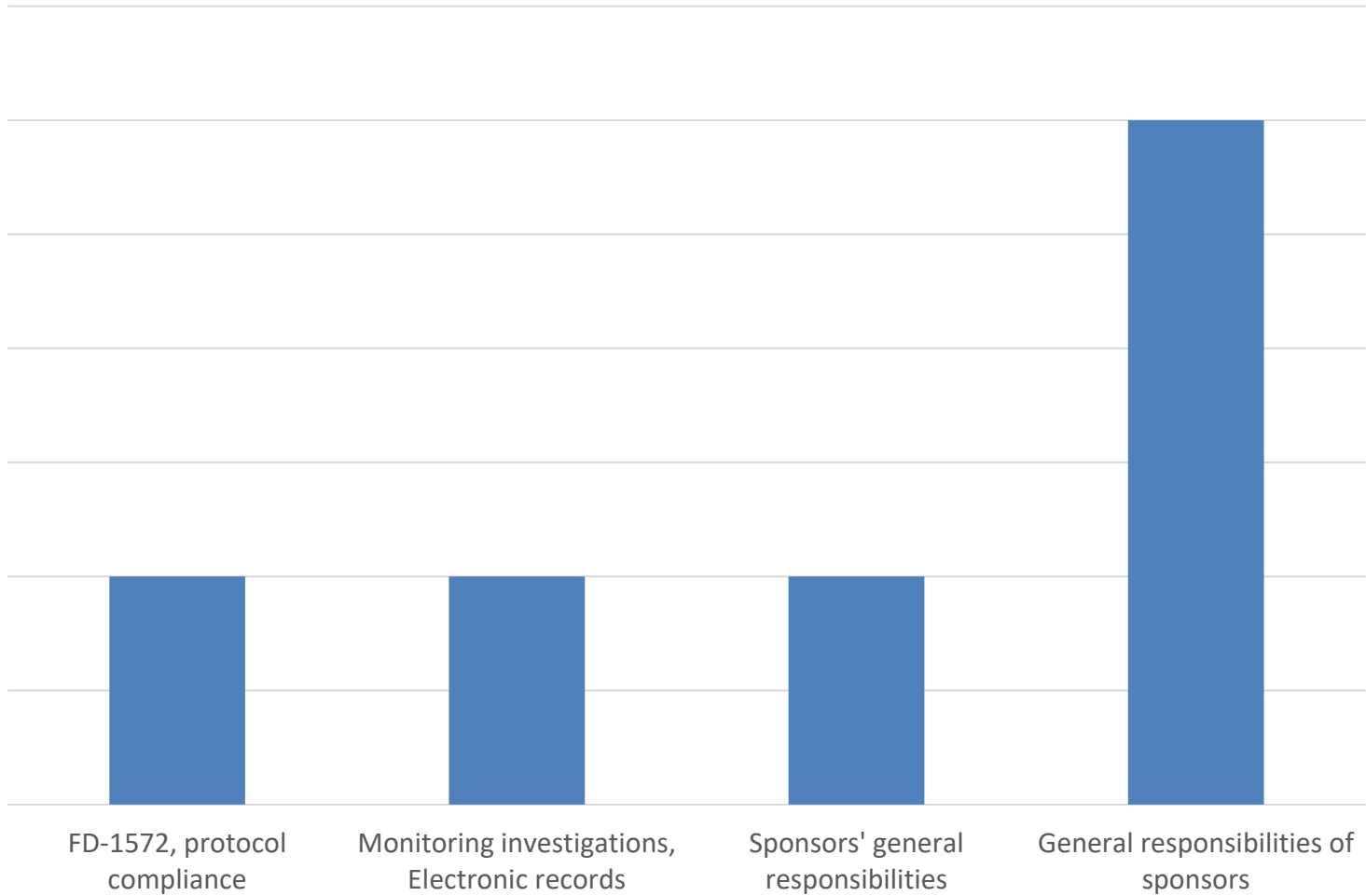
- <http://www.clinicaltrials.gov> statement
- Reasonably foreseeable risks or discomforts
- No elements of 21CFR50.25 included
  - Legally effective consent not obtained
    - Exception to consent not met (COVID testing PCR v Rapid)

## FY 2021 Sponsor 483 Observations Themes for each Cite Reference Number

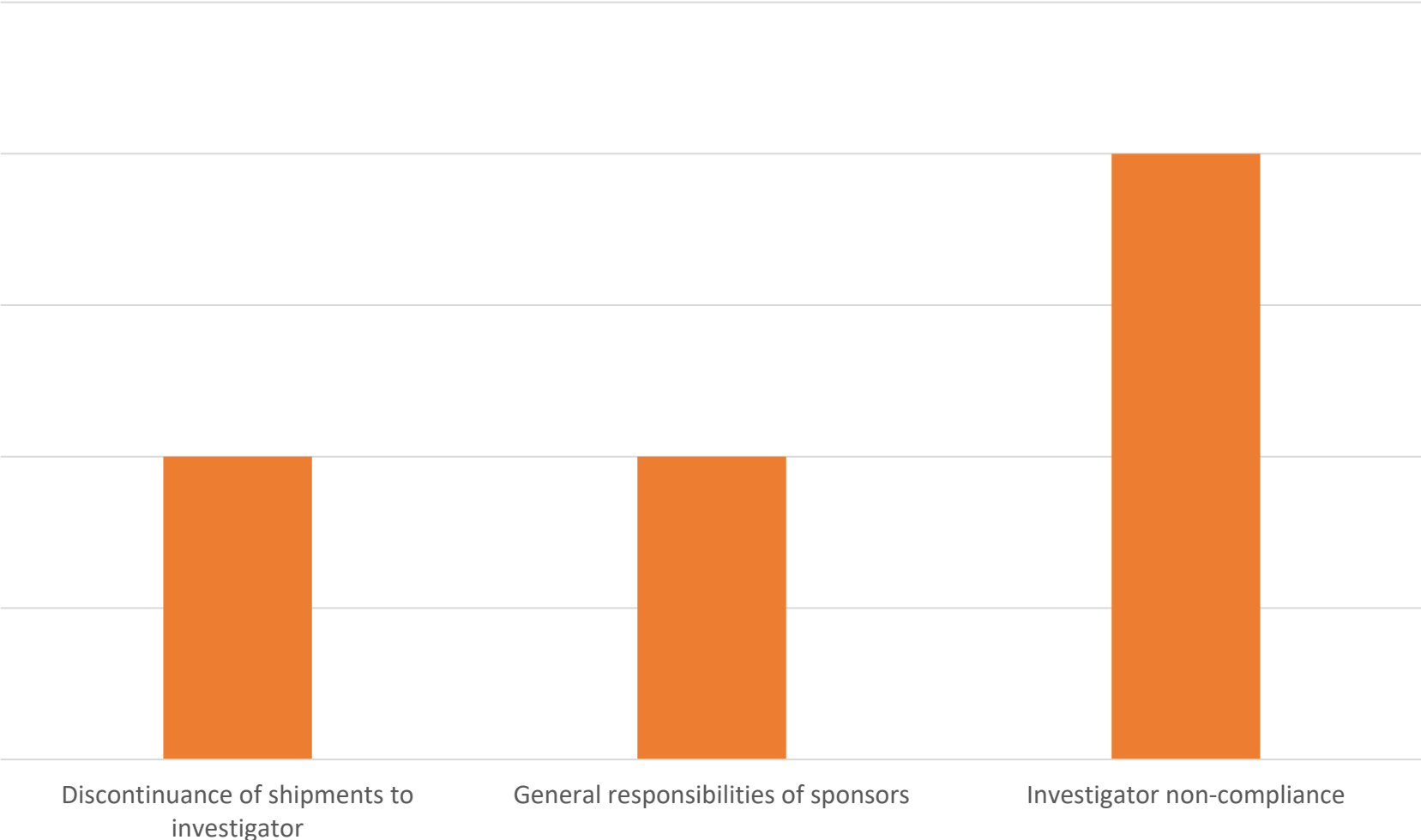




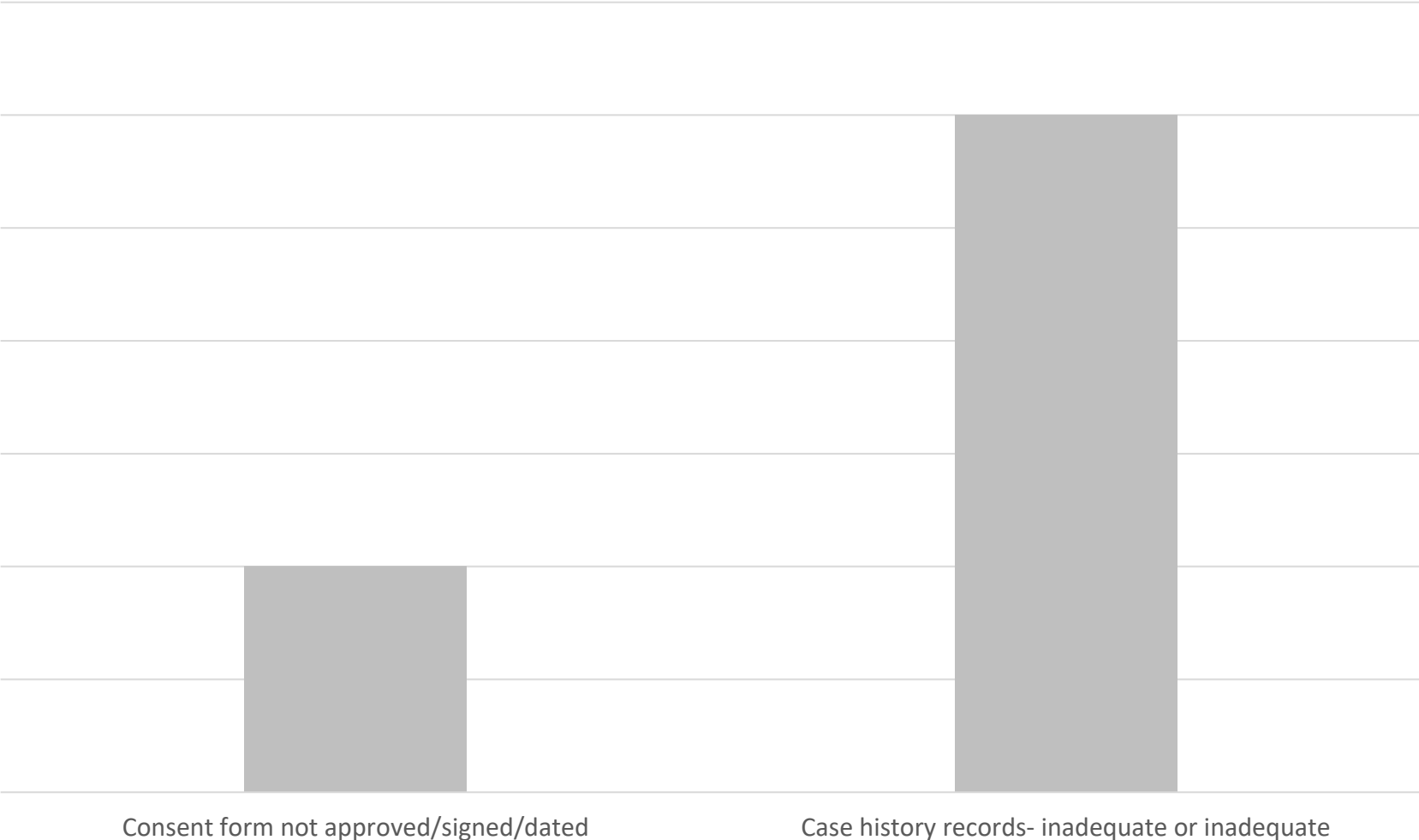
## FY 2021 Sponsor 483 Observations by Inadequate Monitoring Details



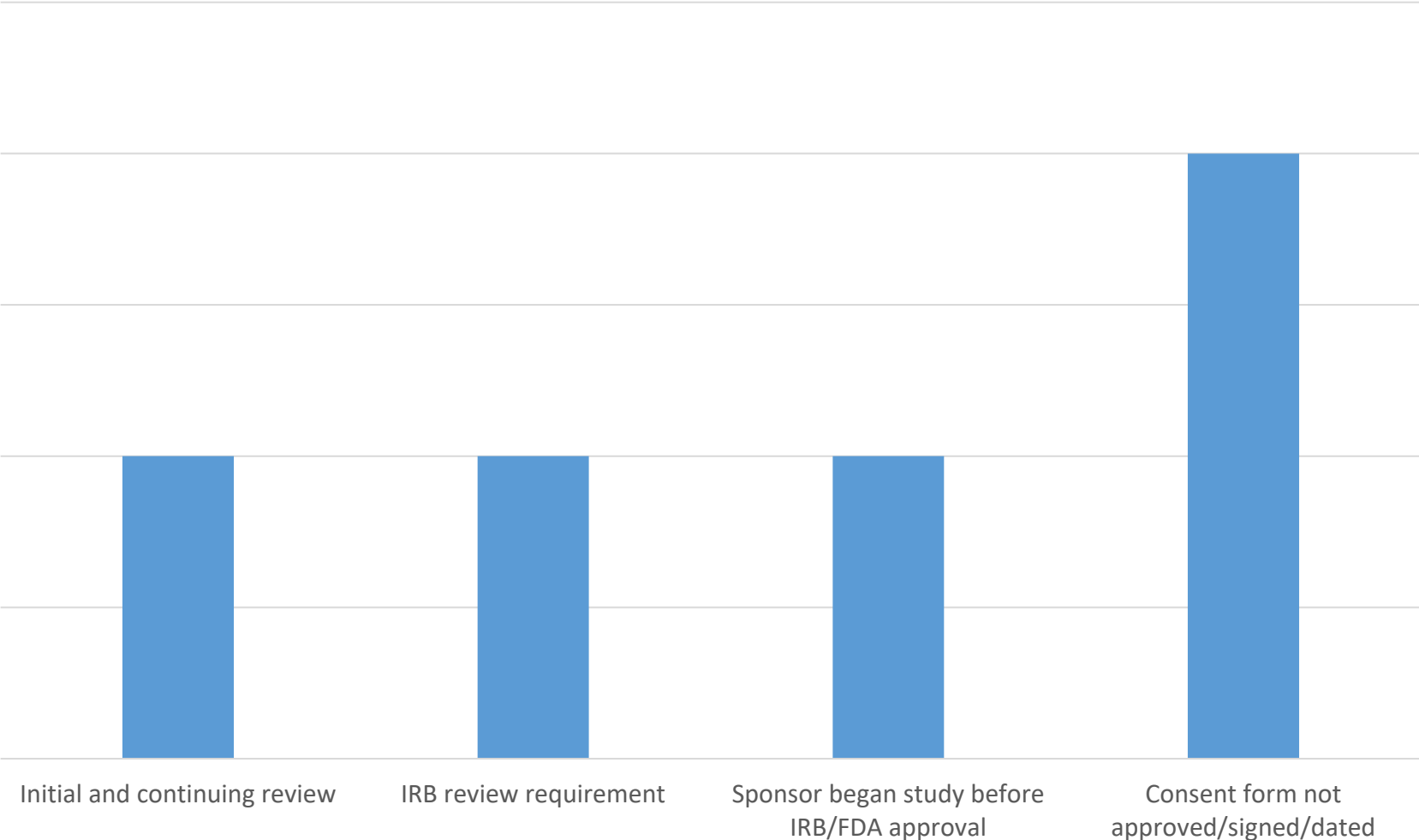
# FY 2021 Sponsor 483 Observations Failure to Secure Compliance Details



# FY 2021 Sponsor 483 Observations Inadequate Case Histories Details



# FY 2021 Sponsor 483 Observations Lack of IRB Approval Details



## FY 2021 Sponsor 483 Observations by Missing ICF Elements Details

