

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Number of IRB, CI & sponsor inspections in calendar year 2014 and 2015
Date: Wednesday, November 04, 2015 6:21:44 AM

Good morning –

I am not aware of any one place that the information you are requesting would be located. You might want to contact some in FDA's Office of Regulatory Affairs (ORA). I have given you a web link to ORA below.

<http://www.fda.gov/ICECI/Inspections/IOM/ucm124051.htm>

Kind regards,

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From: [REDACTED]
Sent: Tuesday, November 03, 2015 10:06 AM
To: OC GCP Questions
Subject: RE: Number of IRB, CI & sponsor inspections in calendar year 2014 and 2015

Thank you for this information. It is very helpful.

One other question I have for you is whether you have statistics on the type/number of enforcement actions, i.e., regulatory or administrative, FDA has taken against CIs/IRBs/Sponsors in FY 2014, e.g., recalls, seizure, closing down of IRBs? I have analyzed FDA warning letters for this time frame, but have not been able to locate other types of regulatory/administrative actions taken. Any help would be greatly appreciated.

[REDACTED]