From: OC GCP Questions
To: [redacted]
Subject: GCP and FWA
Date: Monday, June 12, 2017 6:46:00 AM
Attachments: [redacted]

Good morning –

FDA regulations do not require obtaining a Federalwide Assurance (FWA). Studies conducted under an IND are required to follow FDA regulations, including those for IRB review and obtaining informed consent at 21 CFR parts 50 and 56 (please see links below). Should a study be federally funded and FDA regulated, both FDA regulations and the Common Rule would need to be satisfied and FWA may be required.

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

You can learn more about FWAs by contacting OHRP directly at OHRP@HHS.gov

Kind regards,

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Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, June 08, 2017 4:41 PM
To: OC GCP Questions
Subject: GCP and FWA

Does GCP provide guidance related to FWAs? If a trial is not federally funded are FWAs required? I read on OHRP's website that they are not mandated for non-federally funded trials unless the funding source requires it, but I was wondering if GCP had any guidance related to this.

Thank you.

[redacted]