

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/cfcr/CFRSearch.cfm?CFRPart=50

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

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

Kind regards,

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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.

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