

From: [OC GCP Questions](#)
To: [REDACTED]
Cc: [CDER DRUG INFO](#)
Subject: RE: Signing of ICF
Date: Friday, January 31, 2020 9:59:00 AM
Attachments: [REDACTED]

Dear [REDACTED],

Signing the ICF is not considered part of screening procedures. Obtaining informed consent that is documented by the subject's signature is a stand-alone process that generally occurs prior to initiation of any study-related interventions, with a few exceptions. You may find FDA's information sheet guidance, "Screening Tests Prior to Study Enrollment" useful. It can be found at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/screening-tests-prior-study-enrollment>.

As noted in the above guidance, "...informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research, including withdrawal from medication (wash-out)."

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov.

Best regards,

Sheila

Sheila Brown, RN, MS

Policy Analyst

**Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration**

Tel: 301-796-6563
sheila.brown@fda.hhs.gov



This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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: Wednesday, January 29, 2020 1:23 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>; CDER DRUG INFO <DRUGINFO@fda.hhs.gov>

Subject: Signing of ICF

Good Morning

I am hoping you can assist me.

I am working on a [REDACTED] study and study procedures and IP admin must occur, obviously, after signing of the ICF.

Since subjects are approached while they are [REDACTED] subjects are given the opportunity to review the ICF, take it home to discuss with family then sign with the coordinator at their next [REDACTED] visit.

Since ICF is signed while subject is [REDACTED] the coordinator will perform the screening visit when the subject comes for their next [REDACTED] and perform all study procedures before the [REDACTED] starts.

My question is this:

Is the signing of the ICF considered a screening procedure?

My understanding is the signing of the ICF is not part of screening procedures. Since it must be signed prior to any study procedures being done . This is a document that subject signs to participate in the study.

Thank you

[REDACTED]