From: OC GCP Questions
To: [redacted]
Subject: Blank LAR and witness lines on informed consents
Date: Monday, February 03, 2020 11:03:27 AM
Attachments: [redacted]

Good morning –

FDA regulations are not that specific regarding the scenario you describe below. When the regulations are silent institutions can develop their own standard operating procedures to address a specific situation. I suggest you consult your reviewing IRB to see if they have written internal procedures to address your situation.

The guidance documents below might be helpful to you.

Guide to Informed Consent - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guide-informed-consent

IRB Written Procedures – https://www.fda.gov/media/99271/download

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration

From: [redacted]
Sent: Thursday, January 30, 2020 5:06 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FW: Blank LAR and witness lines on informed consents

Good Afternoon,

I cannot locate any regulations regarding whether or not leaving an unneeded LAR/witness line on a research informed consent is ok. When not applicable, I have seen these leaves left blank while at other times they simply have “N/A” documented when not needed. Do you have any guidance as to what best practice would be in these situations? It seems wrong to leave blank lines on any research documentation.

Thank you so much!

Sincerely,