From: OC GCP Questions
To: [redacted]
Subject: laboratory facilities on the 1572
Date: Tuesday, August 04, 2020 12:27:00 PM
Attachments: [redacted]

Good afternoon –

Thank you for your inquiry. The Form FDA 1572, while an FDA form, is meant for the benefit of the study sponsor - to provide all study-related information in one place and also serve, when signed, as a legal agreement that the clinical investigator will comply with the investigational plan and pertinent regulations. The section on the 1572 meant for listing clinical laboratories used for the study is intended to list the laboratory doing study-specific testing. It is not generally expected that personnel and facilities at the site that perform usual day-to-day procedures common to any patient at the facility are listed on a 1572. However, if it is known that any clinical diagnostics necessary for a study subject on the occasion of an adverse effect or serious adverse effect will be performed by the local laboratory rather than the laboratory otherwise used in the study, it would be useful to inform the sponsor of this by including the laboratory on the 1572 with that caveat. This would allow the sponsor to comment if there are any concerns about this proposed practice.

Please see FDA's guidance on the 1572 form. https://www.fda.gov/media/78830/download

Kind regards,

Doreen M. Kezer, MSN
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From: [redacted]
Sent: Monday, August 03, 2020 5:06 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: laboratory facilities on the 1572

Hello,

I have a question regarding the use of alternative laboratory facilities (for example, facilities closer to the subjects home than the laboratory listed on the 1572) and their need to be listed on the 1572. Based on the current guidance for conduct of trials during COVID-19, from question 19, it looks like we do not have to list the outside facilities on the 1572 as long as the lab tests are routine tests that the facilities perform.

I just wanted to confirm that this is correct, and also ask for clarification on Phase 1 studies that have a primary objective of evaluating efficacy or determining a maximum tolerated dose, and a secondary objective of "To assess safety through the evaluation of incidence and severity of nonserious AEs and SAEs, including irAEs and AESIs."

Can you provide guidance on 1572 labs when there is a safety objective that is based on AEs and SAEs?

Thanks,