

RE: SM04690-OA-11-Layle (428)- Imaging Question

GK

Gloria Keopuhiwa <gkeopuhiwa@artemis-research.com>

Today, 11:44 AM

Meghan Stanley; Brittany Weichers <bweichers@artemis-research.com> ✓

👍 ↻ Reply all | ✓

...

Samumed SM04690-OA-11

You replied on 2/7/2019 11:49 AM.

Hi Meghan,

I just wanted to let you know that there has been an update to the protocol. The subject will no longer need to complete DXA.

Dear Investigator,

The purpose of this memo is to provide notification to all sites that Samumed will be amending current protocol for the above referenced study, Protocol Amendment 00 Version 00, dated 2/7/2019. Significant changes to the protocol that will impact site requirements and the study budget are following:

1. The Dual-Energy X-Ray Absorptiometry (DXA) scan procedure will be removed from the protocol and will no longer be required at any time during the study.

Thank you,

Gloria Keopuhiwa

Lead Clinical Research Coordinator



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Main: 760-266-4144

Fax: 760-266-4140

Email: gkeopuhiwa@artemis-research.com

Web: www.artemis-research.com

From: Meghan Stanley <mstanley@valleyrad.com>

Sent: Thursday, February 07, 2019 11:27 AM

Subject: Re: SM04690-OA-11-Layle (428)- Imaging Question

Anytime, Gloria!

Will get back to you soon with the rest. Appreciate your patience.

Thank you,

Meghan Stanley

Clinical Research Coordinator

Valley Radiology Consultants Medical Group, Inc.

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mstanley@valleyrad.com



From: Gloria Keopuhiwa <gkeopuhiwa@artemis-research.com>

Sent: Thursday, February 7, 2019 11:25:48 AM

To: Meghan Stanley

Cc: Brittany Weichers

Subject: RE: SM04690-OA-11-Layle (428)- Imaging Question

Meghan,

Thank you so much.

Thank you,

Gloria Keopuhiwa

Lead Clinical Research Coordinator



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Email: gkeopuhiwa@artemis-research.com

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From: Meghan Stanley <mstanley@valleyrad.com>

Sent: Thursday, February 07, 2019 11:17 AM

Subject: Re: SM04690-OA-11-Layle (428)- Imaging Question

Hi Gloria,

Please see attached - I have included the date these were signed.
Please let me know if there is anything else you need. I will follow up with the radiologists today and make sure GCP training is completed.

Thank you,

Meghan Stanley

Clinical Research Coordinator

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mstanley@valleyrad.com



From: Gloria Keopuhiwa <gkeopuhiwa@artemis-research.com>

Sent: Thursday, February 7, 2019 11:08:19 AM

To: Meghan Stanley

Cc: Brittany Weichers

Subject: RE: SM04690-OA-11-Layle (428)- Imaging Question

Hi Meghan,

Thanks for getting these back to me, however, both CV's not only have to be signed but also dated. This starts the timeline on that CV. CV's are usually updated every two years, so that will be based off the date on these.

Thank you,

Gloria Keopuhiwa

Lead Clinical Research Coordinator



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From: Meghan Stanley <mstanley@valleyrad.com>
Sent: Thursday, February 07, 2019 8:46 AM
To: Gloria Keopuhiwa <gkeopuhiwa@artemis-research.com>
Cc: Brittany Weichers <bweichers@artemis-research.com>; Meghan Stanley <mstanley@valleyrad.com>
Subject: Re: SM04690-OA-11-Layle (428)- Imaging Question

Good Morning, Gloria!

Attached I have both Dr. Nalbandian and Dr. Luchsinger's signed CV's, as well as Dr. Luchsinger's signed Financial Disclosure Form. Both radiologists will be working on getting the GCP training completed today.

Thank you,

Meghan Stanley
Clinical Research Coordinator
Valley Radiology Consultants Medical Group, Inc.
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O: 760.739.5400, ext. 2324
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From: Meghan Stanley
Sent: Tuesday, February 5, 2019 11:08:55 AM
To: Gloria Keopuhiwa
Cc: Brittany Weichers; Meghan Stanley
Subject: Re: SM04690-OA-11-Layle (428)- Imaging Question

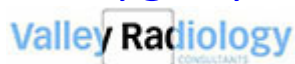
Hi Gloria!

Sounds great. I'll work on getting these completed and get them over to you ASAP.

Thank you,

Meghan Stanley
Clinical Research Coordinator
Valley Radiology Consultants Medical Group, Inc.
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From: Gloria Keopuhiwa <gkeopuhiwa@artemis-research.com>
Sent: Tuesday, February 5, 2019 11:04:35 AM
To: Meghan Stanley
Cc: Brittany Weichers
Subject: RE: SM04690-OA-11-Layle (428)- Imaging Question

Hi Meghan,

I have attached the CV that we received for Dr. Nalbandian. If you could have him sign and date it. I will also need a CV for Dr. Luchsinger as well as a signed Financial Disclosure, and GCP training. The sponsor would like to have this training before they award us the study just to show proof that they are trained and aware of the Good Clinical Practices. I have spoken with our finance team about the exhibit and they are holding onto it until the sponsor has approved the budget.

Thank you,

Gloria Keopuhiwa
Lead Clinical Research Coordinator



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From: Meghan Stanley <mstanley@valleyrad.com>
Sent: Tuesday, February 05, 2019 9:02 AM
To: Gloria Keopuhiwa <gkeopuhiwa@artemis-research.com>
Cc: Brittany Weichers <bweichers@artemis-research.com>; Meghan Stanley <mstanley@valleyrad.com>
Subject: Re: SM04690-OA-11-Layle (428)- Imaging Question

Hi Gloria,

Do you just need his regular CV that we have on file signed? I can get this over to you today, if so. We need to have Dr. Nalbandian as well as Dr. Luchsinger complete GCP training, but in order to do this we need to block some time out for them and wanted to make sure the terms of the Exhibit were agreed upon prior to this. Is this training something that needs to be completed prior to the

Thank you,

Meghan Stanley

Clinical Research Coordinator

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From: Gloria Keopuhiwa <gkeopuhiwa@artemis-research.com>

Sent: Tuesday, February 5, 2019 8:57:22 AM

To: Meghan Stanley

Cc: Brittany Weichers

Subject: RE: SM04690-OA-11-Layle (428)- Imaging Question

Hi Meghan,

I will need Dr. Nalbandian to sign his CV as well as complete the GCP training.

Thank you,

Gloria Keopuhiwa

Lead Clinical Research Coordinator



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From: Meghan Stanley <mstanley@valleyrad.com>

Sent: Tuesday, February 05, 2019 8:17 AM

To: Gloria Keopuhiwa <gkeopuhiwa@artemis-research.com>

Cc: Brittany Weichers <bweichers@artemis-research.com>; Meghan Stanley <mstanley@valleyrad.com>

Subject: Re: SM04690-OA-11-Layle (428)- Imaging Question

Just reaching out to make sure you had all the information you need moving forward in this upcoming trial. Please let me know if there is anything else I can assist with, and please don't hesitate to reach out with any questions.

Thank you,

Meghan Stanley

Clinical Research Coordinator

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From: Meghan Stanley

Sent: Tuesday, January 29, 2019 2:35:09 PM

To: Gloria Keopuhiwa

Cc: Brittany Weichers

Subject: Re: SM04690-OA-11-Layle (428)- Imaging Question

Thank you for that information, Gloria!

I have attached an amended Exhibit for your review, containing pricing for technical component only. Please review, sign and return. As always, should you have any questions regarding the document, please reach out to me.

Thank you again!

Thank you,

Meghan Stanley

Clinical Research Coordinator

Valley Radiology Consultants Medical Group, Inc.

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C: 443.876.4589

F: 760.888.2086

mstanley@valleyrad.com



To: Meghan Stanley
Cc: Brittany Weichers
Subject: FW: SM04690-OA-11-Layle (428)- Imaging Question

Good Afternoon,

Please see below correspondence from the study team with regard to the central read.

Thank you,

Gloria Keopuhiwa
Lead Clinical Research Coordinator



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From: Kokoechat Masek <kokoechat@samumed.com>
Sent: Tuesday, January 29, 2019 2:19 PM
To: Gloria Keopuhiwa <gkeopuhiwa@artemis-research.com>
Subject: RE: SM04690-OA-11-Layle (428)- Imaging Question

Hi Gloria,

There will be a central reader for each:

The rad technicians will acquire and transmit the images electronically to MMI for x-rays and to Bioclinica for DXA scans.

There will be webinars from both Vendors prior to study start.

Please let me know if you have any other questions.

Kind regards,
Kokoechat

Kokoechat Masek, CCRA
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From: Gloria Keopuhiwa <gkeopuhiwa@artemis-research.com>
Sent: Tuesday, January 29, 2019 2:07 PM
To: Kokoechat Masek <kokoechat@samumed.com>
Subject: RE: SM04690-OA-11-Layle (428)- Imaging Question

EXTERNAL

Will they be doing a local read for the xrays and dexa or will there be a central read?

Thank you,

Gloria Keopuhiwa
Lead Clinical Research Coordinator

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Email: gkeopuhiwa@artemis-research.com
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From: Kokoechat Masek <kokoechat@samumed.com>
Sent: Tuesday, January 29, 2019 2:04 PM
To: Gloria Keopuhiwa <gkeopuhiwa@artemis-research.com>
Subject: SM04690-OA-11-Layle (428)- Imaging Question

Hi Gloria,

Could you please ask the imaging facility to provide further clarification on what they are asking for?

Kind regards,
Kokoechat

Kokoechat Masek, CCRA
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From: Gloria Keopuhiwa <gkeopuhiwa@artemis-research.com>
Sent: Tuesday, January 29, 2019 1:57 PM
To: Kokoechat Masek <kokoechat@samumed.com>
Subject: SM04690-AO-11

EXTERNAL

Hi Kokoechat,

The imaging facility is asking if the x-ray and dexa for this study will be tech only or global?

Thank you,

Gloria Keopuhiwa
Lead Clinical Research Coordinator



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