From: Mel, Andrea
To: Elliott, Robin
Subject: [External_Sender] FW: NRC Inspection
Date: Tuesday, March 3, 2020 12:14:38 PM

Hi Robin,

I did find another study we are participating in which you will find below. This is the only site we receive patients from for this study. Let me know if the verbiage in the email below is sufficient or if you would require separate documentation.

I am waiting on response from the other study. As soon as it arrives I will forward to you.

I appreciate your patience,

Andrea

Andrea J Mel
Director Of Clinical Operations
Advanced Radiology
3 Enterprise Drive, Shelton, CT 06484
Office: 203.696.3611
Mobile: 203.218.0992
andrea.mel@adrad.com
www.adrad.com

From: Janet Mauro [mailto:jmauro@assocneuro.com]
Sent: Tuesday, March 3, 2020 11:50 AM
To: Mel, Andrea <Andrea.Mel@adrad.com>
Cc: Dawn Morsey <dmorsey@assocneuro.com>; Dr. Sam Markind <smarkind@assocneuro.com>
Subject: Re: NRC Inspection

Hi Andrea,
I am the Study Coordinator for the I5T-MC-AACG study for the subjects that were sent to ADRAD from Associated Neurologists, PC, Danbury, and I can attest to the fact that our site was IRB-approved to participate in this study and that our subjects signed informed consent documents. I cannot attest to this fact for subjects sent to you from any other sites.

Please tell me what documentation you might need and I'm happy to provide this to you.

Best regards,

Janet Mauro, BA, CCRC
Certified Clinical Research Coordinator

Associated Neurologists, PC
69 Sand Pit Road, Suite 300
Danbury, CT 06810
Phone: (203) 748-2551 x351
Fax: (203) 830-6886
Email: jmauro@assocneuro.com
http://www.associatedneurologists.org

-----Original Message-----
From: "Mel, Andrea" [Andrea.Mel@adrad.com]
Date: 03/03/2020 11:39 AM
To: "jmauro@assocneuro.com" <jmauro@assocneuro.com>
Subject: NRC Inspection

Hi Janet,

I am the Director of Clinical Operations for Advanced Radiology.

We recently had an NRC inspection and they are asking for some additional information regarding clinical research and PET imaging. The inspectors want to be sure the study was approved by an IRB and all patients have given informed consent. They are asking for a statement stating both these things.

Would you be the individual to assist me with this request? I appreciate your help, the NRC is looking to have this wrapped up in a timely fashion.

Regards,

Andrea

Andrea J Mel
Director Of Clinical Operations
Advanced Radiology
3 Enterprise Drive, Shelton, CT 06484
Office: 203.696.3611
Mobile: 203.218.0992
andrea.mel@adrad.com

www.adrad.com

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