From: Rick Cruise
To: Arling, Michelle
Cc: Celeste Duran
Subject: FW: Advarra review of research under 40 CFR 26, Subparts K-L - Pro00042023
Date: Tuesday, June 16, 2020 12:20:29 PM
Attachments: image003.png
Rosenheck Protocol Approval with Modifications Notice Feb2520 - Revised Jun1620.pdf

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Good afternoon, Ms. Arling.

Thank you for your message. I have confirmed that the study was reviewed and approved under the requirements of 40 CFR 26, Subparts K-L.

Also, the study does have a 12 month Continuing Review interval and the statement in the notice regarding no continuing review being required is incorrect.

I have posted a revised approval notice that corrects both oversights in our CIRBI platform and have notified Leah Rosenheck as well.

The revised notice is also attached here. Please accept my apologies for any confusion this may have created.

Thank you. Have a good day.

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From: Arling, Michelle <Arling.Michelle@epa.gov>
Sent: Monday, June 15, 2020 8:52 AM
To: Julie Blasingim <Julie.Blasingim@advarra.com>; April Hatley <April.Hatley@advarra.com>; Jeffrey Atlas <Jeffrey.Atlas@advarra.com>
Subject: Advarra review of research under 40 CFR 26, Subparts K-L - Pro00042043

CAUTION: External email

Good morning,

I work at the US Environmental Protection Agency, and I review protocols and studies for research involving intentional exposure of human subjects to determine whether they comply with EPA's

regulation at 40 CFR 26, Subparts K-L (based on the Common Rule) governing this type of research. We have corresponded in the past about research that has been reviewed and approved by Advarra prior to submission to EPA.

I'm reaching out to you now with a concern about a protocol approved with modifications that has been submitted to EPA for review. The attached notes that the research is not subject to continuing review. Here's the text at 40 CFR 26.1109(f) for waiving continuing review:

> (f)(1) Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:
>
> > (i) Research eligible for expedited review in accordance with §26.1110;
> >
> > (ii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
> >
> > > (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
> > >
> > > (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

I have 2 concerns – first, the approval references that continuing review is not required <u>under the Common Rule</u>. This is not accurate because this research is subject to the requirements at 40 CFR 26, Subparts K-L, as it is not conducted or sponsored by a federal agency and therefore not subject to the requirements of the Common Rule. Please confirm that when Advarra is reviewing research subject to the requirements of 40 CFR 26, Subparts K-L, it is applying all applicable standards from this part of EPA's regulation.

Second, the research does not seem to meet any of the conditions listed in the regulation for waiving continuing review. The proposed research is not eligible for expedited review, nor has it progressed to the point that it includes data analysis or accessing follow-up clinical data.

Can you please explain why the approval letter indicates that no continuing review is required?

This protocol will be amended and resubmitted prior to implementation, following review by the EPA and the Human Studies Review Board, as required at 40 CFR 26, Subpart P. I want to ensure that the final, unconditional approval reflects the IRB review requirements at 40 CFR 26, Subparts K-L, including the requirement for this research to be subject to continuing review.

Please feel free to call or email me if you have any questions.

Michelle Arling
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