Laura Cortes

From: Parineeta Ghosh <parineeta@doctors.org.uk>
Sent: 11 October 2024 12:31
To: eFONA
Cc: Iain Moppett; Alistair McNarry
Subject: Fwd: IRAS 330418

Begin forwarded message:

From: Rachel Katzenellenbogen <Rachel.Katzenellenbogen@hra.nhs.uk>
Subject: RE: IRAS 330418
Date: 11 October 2024 at 12:28:50 BST
To: Parineeta Ghosh <parineeta@doctors.org.uk>

Hi Parineeta.

I can confirm CAG was not required as the study would not breach the common law duty of confidentiality.

If it being in the protocol is proving problematic, I would recommend you remove it. It should be a simple enough amendment.

Best wishes,
Rachel

Rachel Katzenellenbogen (she/her)
Approvals Specialist
Health Research Authority
T. 207 104 8012
W.www.hra.nhs.uk
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From: Parineeta Ghosh <parineeta@doctors.org.uk>
Sent: Friday, October 11, 2024 8:00 AM
To: Leeds East <leedseast.rec@hra.nhs.uk>
Cc: Iain Moppett <iain.moppett@nottingham.ac.uk>; Alistair McNarry <althegasman@btinternet.com>
Subject: IRAS 330418

Dear Rachel,

Hope you're well. I was hoping would be able to help us clarify another matter. We are in the process of confirming C&C for the eFONAr.

There has been some query from R&D's about CAG as the protocol mentioned we would be seeking it.

We weren't sure whether we should be amending this given that was the version approved by HRA upon submission. Instead, wondering if it would be possible to provide some evidence that CAG was sought but deemed not needed by HRA which we could send to site R&D's to clarify this.

Many thanks in advance,

BW,

Parineeta

On 16 Sep 2024, at 08:08, Leeds East <leedseast.rec@hra.nhs.uk> wrote:

Hi Parineeta.

Thank you for your email.

I'm at a bit of a loss here, because I approved an OID and SoE when I approved the study and both are listed on the HRA Approval letter.

All I can suggest is you go back to Northern Ireland and let them know the OID and SoE have been approved.

It's interesting you say NI **ethics**, because of course this study did not require ethical review. Perhaps that's their concern?

Sorry I can't be more help.

Regards,
Rachel

Rachel Katzenellenbogen (she/her)
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From: Parineeta Ghosh <parineeta@doctors.org.uk>
Sent: Thursday, September 12, 2024 4:42 PM
To: Leeds East <leedseast.rec@hra.nhs.uk>
Cc: Iain Moppett <iain.moppett@nottingham.ac.uk>; Alistair McNarry <althegasman@btinternet.com>
Subject: IRAS 330418 - clarification of OID
Importance: High

Dear Rachel,

Hope you're doing well. I was hoping you could help me clarify something regarding the approval process. I was under the impression that HRA have granted approval for England and Wales for EFONAR project to commence.

Upon speaking to the Northern Ireland ethics representative, we've just been told that OID is not in place. I've attached the documents previously approved by the sponsor.

Could you please advise what steps need to be taken next. We are at a stage to start data collection and keen to resolve this.

Thank you!

Best wishes,

Parineeta
eFONA fellow

From: leedseast.rec@hra.nhs.uk <noreply@harp.org.uk>
Date: Wednesday, 17 January 2024 at 11:16
To: Iain Moppett (staff) <mszikm@exmail.nottingham.ac.uk>
Cc: sponsor@nottingham.ac.uk <sponsor@nottingham.ac.uk>
Subject: IRAS 330418. REC Application Valid under Consideration

Dear Prof Moppett,

Thank you for submitting the above application.

This review is comprised of the ethical review undertaken by the Research Ethics Committee (REC) and an Assessment to check compliance with the UK Study-wide governance criteria, as well as relevant additional nation specific areas of review, details of which can be found here.
I have checked the documentation and the following further information needs to be provided in order for us to proceed with the review of the application. Please ensure that this is provided by 19 January 2024.

REC Review - Further Information Required

Please provide the following further information in order for your application to be valid for ethical review by the Research Ethics Committee at your selected meeting. This information must be provided by the date indicated above date in order for the application to be reviewed at your selected meeting.

1. The IRAS form says a member of the clinical care team will enter data into the study database, anonymising it in the process. This means no one outside of the clinical care team will have access to identifiable patient data. Please explain, therefore, why an application to the Confidentiality Advisory Group (CAG) has been made. **Note:** if the study does not require CAG support, then it will also not require REC review. HRA Assessment will, however, still be required.
2. Please submit the documents that will be used to advertise the study.

Assessment - Further information Required

Please provide the following further information in order for your application to be complete for Assessment purposes and to enable me to issue the initial assessment letter.

1. A request was made for the need for site contracts to be waived. This cannot be done as you are asking sites to process data on behalf of the sponsor and, therefore, an agreement must be in place. Therefore, please submit an Organisation Information Document (OID) and Schedule of Events (SoE).

Resubmission guidance

Please submit the requested documents electronically through IRAS following the guidance available here.
To enable your application to progress without delay we encourage you to provide your responses as soon as possible within the timeframes specified. Please do not hesitate to contact us if you have any questions or if you would like to request additional time to respond.

Kind regards

Rachel Katzenellenbogen
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