Gmail **Steve Nixon <steve.nixon.viamed@googlemail.com>**

Fwd: RE: IRAS 222270 Request for clarifications following Initial HRA Assessment

1 message

Heather Elphick <Heather.Elphick@sch.nhs.uk> 17 March 2017 at 12:17
To: Samya Armoush <Samya.Armoush@sch.nhs.uk>
Cc: Patrick Trotter <p.trotter@medilink.co.uk>, Tom Wright <t.wright@medilink.co.uk>, "FadiJ@nonwovens-innovation.com" <FadiJ@nonwovens-innovation.com>, Ruth Kingshott <Ruth.Kingshott@sch.nhs.uk>, Steve Nixon <steve.nixon@viamed.co.uk>

Hi Samya,

The HRA have responded as attached with regards to the oximetry algorithm study. I have addressed their queries and have chosen option a) for a combined response to HRA and REC. I'll forward the REC response and amended documents in a separate email.

Thanks
Heather

——— Forwarded message ———
From: "Thomas (HEALTH RESEARCH AUTHORITY) FAIRMAN" <thomas.fairman@nhs.net>
To: Heather Elphick <Heather.Elphick@sch.nhs.uk>
Cc: "NRESCommittee.London- (HEALTH RESEARCH AUTHORITY) CITYANDEAST" <nrescommittee.london-cityandeast@nhs.net>, Jane Pearson <Jane.Pearson@sch.nhs.uk>, Wendy Swann <Wendy.Swann@sch.nhs.uk>
Bcc:
Date: Mon, 13 Mar 2017 11:20:54 +0000
Subject: RE: IRAS 222270 Request for clarifications following Initial HRA Assessment

Dear Heather,

Thank you for this response, which looks great. I will look forward to seeing any amended documents following the REC meeting. I have drafted the HRA Approval letter so will be able to issue this as soon as the REC process is complete.

Many kind regards

Tom

Thomas Fairman | HRA Assessor

Health Research Authority
Bristol HRA Centre, Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT
E-mail thomas.fairman@nhs.net | T: 02071 048 112

| www.hra.nhs.uk

From: Heather Elphick [mailto:Heather.Elphick@sch.nhs.uk]
Sent: 11 March 2017 11:16
To: FAIRMAN, Thomas (HEALTH RESEARCH AUTHORITY) <thomas.fairman@nhs.net>
Cc: CITYANDEAST, NRESCommittee.London- (HEALTH RESEARCH AUTHORITY) <nrescommittee.london-cityandeast@nhs.net>; Jane Pearson <Jane.Pearson@sch.nhs.uk>; Wendy Swann <Wendy.Swann@sch.nhs.uk>
Subject: Re: IRAS 222270 Request for clarifications following Initial HRA Assessment

Dear Thomas,

Thanks very much for your email.

In response to your queries,

1) RK and HE (who are members of both the NHS clinical and research teams) will be accessing the records for both screening purposes and to obtain the data needed for the data collection form in Appx 1. The data in this form are needed by Viamed for the purposes of CE marking the device. The data will be anonymised by RK by assigning each patient a unique study number prior to sending the data to Viamed. The data needed are: date of oximetry, age at time of oximetry, height, weight, gender, ethnicity, reason for oximetry, co-morbidities. The patient won't be identifiable from this data.

2) RK and HE (who are members of both the NHS clinical and research teams) will have access to the NHS patient record and may need to access this if required for the CE marking. The rest of the research team will not have access to the patient records. The unique study number which will link the patients to their identifiable hospital information will be saved on an encrypted NHS computer for up to 12 months after the study end and only RK and HE will have access to them. Personal identifiable data will not be stored, but I ticked this box on the IRAS form as the unique study number will link to the patient's medical record.

I hope this clarifies your queries. Please let me know if you need any more information.

I'd prefer to submit one response to both yourself and the REC team with the amended documents if this is acceptable to REC.

Dear NRES committee, I'd be grateful if you could confirm that this is acceptable to you?

Thanks very much

Heather

Prof Heather Elphick

Consultant in Paediatric Respiratory and Sleep Medicine

MB ChB MRCP MD

Tel 0114 2717621, Secretary 0114 2717400

Email Heather.Elphick@sch.nhs.uk

>>> "FAIRMAN, Thomas (HEALTH RESEARCH AUTHORITY)" <thomas.fairman@nhs.net> 10/03/2017 10:17 >>>

Dear Professor Elphick,

RE: IRAS 222270, Paediatric Oximetry Algorithms

Thank you for submitting your application for HRA Approval. I have conducted an initial assessment of your application and I am contacting you to request some further information which is outstanding for HRA Approval. I have copied the REC into this email so that they are aware of the changes and clarifications that have been requested.

Further information for the purposes of HRA Assessment

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Please can you provide the further clarifications as detailed below and confirm by email that you will make the requested amendments to study documents to enable me to fully understand the application and comply with HRA Approval standards. Please do not submit any amended documents until after the initial REC review of your study. You can then follow the most appropriate of the two options below.

1) I note that you state, at IRAS A36 that "Medical records will be accessed by RK or HE, who are both members of the healthcare team, to obtain the necessary patient information'. Please can you clarify if this access will be for the purposes of screening or to capture further patient data for study purposes. If the later please can you detail in the PIS that you will access participants notes to collect additional data and detail what data will be collected and why this is necessary.

2) Please can you clarify why it is necessary to retain personal identifiable data, as opposed to anonymised research data, for a period of 6 - 12 following the end of the study, as detailed at IRAS A43, particularly as you state, at IRAS A36 that the research team will not have access to this. If you will retain identifiable data please can you detail in the PIS what data will be retained, the purpose of this, how the data will be secured and accessed and for how long it will be retained for.

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Options for submission of amended study documents

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You can either

a) Submit one response with amended documents incorporating both the changes requested above and those requested by REC. If you wish to follow this route please can you contact the REC manager before doing so to confirm that this would be acceptable to the REC and, when making changes, clearly differentiate between those made for my purposes and those made following requests from the REC.

b) Alternatively you can submit a response to the REC making only the changes that they have requested. Following the completion of the REC review of the study you can then make the further changes requested by myself and email the final documents to me.

In this case you should ask the sponsor to consider whether the further changes made are considered a substantial or non-substantial amendment. If non-substantial then you should obtain written confirmation of this and forward it to me with the amended documents. No additional notification to the REC is required.

If substantial then you should arrange to submit the documents to the REC in the normal manner in addition to emailing them to me. Once this amendment has been approved please notify me and I will then be able to issue HRA Approval.

I will look forward to hearing from you. If you have any queries or concerns please do not hesitate to contact me.

Kind regards

Thomas Fairman

HRA Assessor

Thomas Fairman | HRA Assessor

Health Research Authority

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