

Joanne Lucas

From: CAG <cag@hra.nhs.uk>
Sent: 16 August 2024 10:46
To: Joanne Lucas
Cc: Claire Rourke; SWiFT; Viona Rundell
Subject: RE: Urgent request for advice: SWiFT Trial - 22CAG0050; IRAS 300414

Follow Up Flag: Follow up
Flag Status: Completed

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Hi Jo,

So none of this is any breach of confidentiality. There is no processing of identifiers without consent, and outside the direct care team at any point, either to send the letters, or collect the data. I am not sure if you have to send the letters – that is up to you and REC to consider - As there is no breach of confidentiality, those processes would not require you to seek either consent or s251, under common law.

You can do this process without 's251' support, no CAG amendment required – we can just save this correspondence as notification only.

Thanks

Caroline Watchurst
Confidentiality Advisor

Health Research Authority

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From: Joanne Lucas <Joanne.Lucas@nhsbt.nhs.uk>
Sent: Friday, August 16, 2024 10:43 AM
To: CAG <cag@hra.nhs.uk>
Cc: Claire Rourke <Claire.Rourke2@nhsbt.nhs.uk>; SWiFT <SWiFT@nhsbt.nhs.uk>; Viona Rundell <Viona.Rundell@nhsbt.nhs.uk>
Subject: RE: Urgent request for advice: SWiFT Trial - 22CAG0050; IRAS 300414

Hi Caroline,

NHSBT will not have any keys between study code and identifiers – the clinicians hold that.

With best wishes, Jo

Joanne Lucas 

My pronouns are she/her/hers

Clinical Trial Manager – Study of Whole Blood in Frontline Trauma (SWiFT)

NHS Blood and Transplant Clinical Trials Unit, Cambridge

Twitter @SWiFT_trial

Email swift@nhsbt.nhs.uk

Visit <http://www.nhsbt.nhs.uk/clinical-trials-unit/>

From: CAG <cag@hra.nhs.uk>

Sent: Friday, August 16, 2024 10:38 AM

To: Joanne Lucas <Joanne.Lucas@nhsbt.nhs.uk>

Cc: Claire Rourke <Claire.Rourke2@nhsbt.nhs.uk>; SWiFT <SWiFT@nhsbt.nhs.uk>; Viona Rundell <Viona.Rundell@nhsbt.nhs.uk>

Subject: RE: Urgent request for advice: SWiFT Trial - 22CAG0050; IRAS 300414

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Hi Jo,

But you will not have access to any key between participants unique study number and identifiers? Is that correct? Only the treating clinical service would hold that?

Thanks

Caroline Watchurst

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From: Joanne Lucas <Joanne.Lucas@nhsbt.nhs.uk>

Sent: Friday, August 16, 2024 10:32 AM

To: CAG <cag@hra.nhs.uk>

Cc: Claire Rourke <Claire.Rourke2@nhsbt.nhs.uk>; SWiFT <SWiFT@nhsbt.nhs.uk>; Viona Rundell <Viona.Rundell@nhsbt.nhs.uk>

Subject: RE: Urgent request for advice: SWiFT Trial - 22CAG0050; IRAS 300414

Hi Caroline,

Thank you for your speedy reply and advice – I have attached the data we wish to collect.

The only identifier will be the participants unique study number.

With best wishes, Jo

Joanne Lucas 

My pronouns are she/her/hers

Clinical Trial Manager – Study of Whole Blood in Frontline Trauma (SWiFT)

NHS Blood and Transplant Clinical Trials Unit, Cambridge

Twitter @SWiFT_trial

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From: CAG <cag@hra.nhs.uk>

Sent: Friday, August 16, 2024 10:23 AM

To: Joanne Lucas <Joanne.Lucas@nhsbt.nhs.uk>

Cc: Claire Rourke <Claire.Rourke2@nhsbt.nhs.uk>; SWiFT <SWiFT@nhsbt.nhs.uk>; Viona Rundell <Viona.Rundell@nhsbt.nhs.uk>

Subject: RE: Urgent request for advice: SWiFT Trial - 22CAG0050; IRAS 300414

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Hi,

You haven't actually stated what data it is you wish to use without consent and outside the direct care team. You have only said - use their data up to the 24 hour time point collected by air ambulance services.

You do not need an amendment to CAG to send the letter – you have said the letter will be sent by clinical teams, so there is no breach of confidentiality to do that. You will need to amend your REC only, not your CAG – for the sending of the letters.

If the clinical teams extract a dataset that does not contain any identifiers and sends that to you, you do not need CAG for that. You also would not necessarily need to send a letter about that. The clinical teams have access to identifiers and could extract a non identifiable dataset and send to NHSTB without being in breach of common law, and so would not need CAG.

If you wish to extract identifiers from the clinical teams to send to NHSBT you would need CAG support for that flow, and the letter sent should be provided as an opt out option, but the actual sending of the letter does not require CAG support. If you could confirm exactly what identifiers you plan to collect, then I can advise better.

Thanks

Caroline Watchurst

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From: Joanne Lucas <Joanne.Lucas@nhsbt.nhs.uk>

Sent: Friday, August 16, 2024 10:01 AM

To: CAG <cag@hra.nhs.uk>

Cc: Claire Rourke <Claire.Rourke2@nhsbt.nhs.uk>; SWiFT <SWiFT@nhsbt.nhs.uk>; Viona Rundell <Viona.Rundell@nhsbt.nhs.uk>

Subject: Urgent request for advice: SWiFT Trial - 22CAG0050; IRAS 300414

Importance: High

Study title: A Multi-Centre Randomised Controlled Trial of the Clinical and Cost Effectiveness of Pre-Hospital Whole Blood Administration versus Standard Care for Traumatic Haemorrhage (SWiFT).
CAG ref: 22CAG0050
REC: 22/SC/0072
IRAS: 300414

Dear Confidentiality Advisory Group,

I am writing to ask for your urgent advice.

SWiFT is a pre-hospital emergency medicine blood transfusion trial, comparing standard care blood products with whole blood in those with life-threatening bleeding.

As the patients taking part in the trial are severely injured, the air ambulance services would normally take them to a major trauma centre (MTC) for treatment. In our study, these MTC's are our receiving hospitals. Occasionally though, if the patients are so severely unwell that they would not survive the flight time to an MTC, more blood is immediately needed, or they are suffering a cardiac arrest, some may be admitted to the nearest (non-MTC) hospital for life-saving treatment. In addition, there are some cases where patients were injured in remote locations and an MTC was a long flight away, or if the helicopter was low on fuel, they would be taken to a local hospital. Originally, we expected that only a few patients would be taken to non-participating hospitals, and there is provision in our protocol to ask the non-participating hospital to collect a 'core' dataset (data from arrival to 24 hours) and provide that to us as long as their R&D office permits it (we approach the R&D office).

Not only have we had more patients go to non-participating hospitals than expected, but we have encountered considerable difficulty in obtaining information from non-participating hospitals. Of the 47 patients taken to these hospitals, we only have data for 04. Most non-participating hospitals will either refuse or require a data sharing agreement (which can take many months). We have no way of contacting these patients, nor do any of our receiving hospitals, as the patient is at a different Trust, and there is no way to inform the participants that they are in the trial or undertake follow-up data collection.

We are currently preparing an amendment, which includes a letter to participants who were taken to non-participating hospitals, sent from the air ambulance service that treated them, telling them about the trial. It contains information about the trial and who to contact if they have any questions. We are proposing an opt-out approach – participants will need to contact us to withdraw or have their data deleted. If we do not hear from them, we will use their data up to the 24 hour time point collected by air ambulance services (who already have this data). We would like to collect this data retrospectively and prospectively. We do not plan to send letters to those participants who entered the study retrospectively, as this could potentially cause psychological harm and set back their recovery (e.g. if they are suffering from PTSD). No personally identifiable data would be provided to NHSBT from the air ambulance services, letters would be sent from their clinical teams.

I have attached the information that we expect to collect.

Please can you advise if this is an acceptable proposal?

We are hoping to submit the amendment next week, so it would be much appreciated if our query was expedited.

With best wishes, Jo

Joanne Lucas 

My pronouns are she/her/hers

Clinical Trial Manager – Study of Whole Blood in Frontline Trauma (SWiFT)

NHS Blood and Transplant Clinical Trials Unit, Cambridge

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