

Joanne Lucas

From: CAG <cag@hra.nhs.uk>
Sent: 14 June 2024 10:15
To: Joanne Lucas
Cc: SWiFT; Claire Rourke
Subject: RE: SWiFT Trial amendment 06 - 22CAG0050; IRAS 300414

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Perfect – we will mark down as for notification only.

No need to send us anything else!

Thanks

Caroline Watchurst
Confidentiality Advisor
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W. www.hra.nhs.uk / [Guidance for CAG applicants - Health Research Authority \(hra.nhs.uk\)](#)

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From: Joanne Lucas <Joanne.Lucas@nhsbt.nhs.uk>
Sent: Friday, June 14, 2024 9:49 AM
To: CAG <cag@hra.nhs.uk>
Cc: SWiFT <SWiFT@nhsbt.nhs.uk>; Claire Rourke <Claire.Rourke2@nhsbt.nhs.uk>
Subject: RE: SWiFT Trial amendment 06 - 22CAG0050; IRAS 300414

Hi Caroline,

There is no change to our original application for CAG support in amendment 06.

Would you like copies of the documents in this amendment for your records?

With best wishes, Jo

Joanne Lucas  

My pronouns are she/her/hers

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

Work phone **07385 964391**

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

From: CAG <cag@hra.nhs.uk>
Sent: Thursday, June 13, 2024 5:52 PM
To: Joanne Lucas <Joanne.Lucas@nhsbt.nhs.uk>
Cc: SWiFT <SWiFT@nhsbt.nhs.uk>; Claire Rourke <Claire.Rourke2@nhsbt.nhs.uk>
Subject: RE: SWiFT Trial amendment 06 - 22CAG0050; IRAS 300414

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Hi Jo,

That is correct, you do not need to fill in a CAG amendment form if there is no change to your 's251' support. We will accept as notification by email.

I think this change is ok for notification only, however please can you confirm? so long as this is no change to your 's251' support, then no CAG amendment required and we can accept as notification only, however the amendment tool only kicks out what you put in, and so is slightly fallible – and therefore will only show a CAG amendment is required if area of change is ticked as 'confidential patient information arrangements'.

I have read the description of the changes but am not 100% sure from what you have entered into the tool with regards to 's251' support. We will accept your word for it if there is no change to 's251' support, but please can you confirm by email first, so I do not depend only on the output of the tool?

Thanks

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From: Joanne Lucas <Joanne.Lucas@nhsbt.nhs.uk>
Sent: Tuesday, June 11, 2024 2:56 PM
To: CAG <cag@hra.nhs.uk>
Cc: SWiFT <SWiFT@nhsbt.nhs.uk>; Claire Rourke <Claire.Rourke2@nhsbt.nhs.uk>
Subject: SWiFT Trial amendment 06 - 22CAG0050; IRAS 300414

Dear Confidentiality Advisory Team,

We have submitted an amendment to the HRA – I have attached the amendment tool that lists the changes. It has been designated "Notification Only" for CAG, do we still need to fill in an amendment form when it doesn't require CAG approval, as it doesn't affect our CAG support?

With best wishes, Jo

Joanne Lucas  

My pronouns are she/her/hers

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

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