

**From:** [Surrey Borders](#)  
**To:** [ukremap-cap](#)  
**Subject:** RE: REMAP-CAP / IRAS 237150 / REC 18/LO/0660 - Query re ISFs  
**Date:** 19 November 2024 09:53:51  
**Attachments:** [image001.png](#)

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Dear Aisha

Thank you for clarifying. Yes, this seems like a sensible approach, and we would have no concern from a governance or ethical perspective.

Kind regards

Alex

**Alex Martin**

**Approvals Specialist**

**Health Research Authority**

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**Usual working hours: 0800-1600**

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**From:** ukremap-cap

**Sent:** 13 November 2024 16:44

**To:** Surrey Borders

**Cc:** ukremap-cap

**Subject:** RE: REMAP-CAP / IRAS 237150 / REC 18/LO/0660 - Query re ISFs

Hello,

Sorry, just to clarify, over covid sites stored study documents electronically on their nhs network drives etc. as we couldn't provide paper files, but NOT in an eISF and they don't have arrangements to archive electronically in a GCP compliant manner or with the required quality assurance.

Hence, they will need to print paper ISFs retrospectively now. As you know ISFs contain study documents that overlap with our central TMF so we are asking if we can omit printing these and instead place a file note in the paper ISF to refer to our TMF for these (protocol, procedure manuals etc.). So the site will have minimal documentation to print.

Kind regards

Aisha



UK REMAP-CAP Clinical Trial Manager

Imperial College London / ICNARC

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**From:** Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>

**Sent:** 11 November 2024 15:21

**To:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Subject:** RE: REMAP-CAP / IRAS 237150 / REC 18/LO/0660 - Query re ISFs

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Dear Aisha

Apologies for the delay in responding.

Please could you further explain to me the process – what is meant by ‘a file note to location reference’?

As far as I am aware there is no requirement to print and archive this documentation. As long as there are processes in place to protect the data you hold electronically, and this data can be accessed easily in a readable format, I think your approach below is acceptable.

There should not be any ethical concerns that a REC should consider here, either.

Thank you

Kind regards

Alex

**Alex Martin**

**Approvals Specialist**

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**From:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Sent:** 04 November 2024 17:31

**To:** Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>

**Cc:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Subject:** RE: REMAP-CAP / IRAS 237150 / REC 18/LO/0660 - Query re ISFs

Hello,

I hope you are well.

Apologies for yet another ISF query.

For sites that stored study documents electronically during the covid period (as we were not able to provide paper ISFs) we wondered if ISF documents that are held centrally in our TMF could avoid being printed for ISF archiving, and if we could instead put a File Note for location reference?

This would be for documents like the protocol, all amendments, old templates, procedural manuals etc.

The reason we ask is because printing all the documents from covid until now would be 1500 pages+ per ISF (due to the many and fast changes over covid) and it is a rather laborious task for

sites – many of whom have now asked us to do this centrally due to capacity and printing limitations, but we ourselves have similar issues in printing such large amounts of paper. This would be for our covid sites only, as our new sites that are open/opening for flu are being sent full paper ISFs by us.

We look forward to hearing from you.

Kind regards

Aisha



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**From:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Sent:** 20 August 2024 17:36

**To:** Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>

**Cc:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Subject:** RE: REMAP-CAP / IRAS 237150 / REC 18/LO/0660 - Query re ISFs

Hi Alex,

Many thanks for this.

Kind regards

Aisha

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**From:** Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>

**Sent:** Tuesday, August 20, 2024 10:20 AM

**To:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Subject:** RE: REMAP-CAP / IRAS 237150 / REC 18/LO/0660 - Query re ISFs

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Hi Aisha

Thank you for your patience. The Chair of the REC responded with the following:

*On the assumption that the ISF doesn't include any confidential patient information - in which case requisite data protection mechanisms would need to be applied for controlled storage and plans for destruction at a pre-defined time.*

*If there's no confidential data then I don't believe this is an ethical issue - more of a procedural and quality management issue.*

I would suggest that you are free to proceed as you wish in this instance, as we have no further guidance to offer?

Thank you

Kind regards

Alex

**Alex Martin**

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**From:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Sent:** Monday, August 12, 2024 1:23 PM

**To:** Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>

**Cc:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Subject:** RE: REMAP-CAP / IRAS 237150 / REC 18/LO/0660 - Query re ISFs

Hi Alex,

The sponsor are pragmatic but want to ensure this isn't against ethics/regulations to archive an ISF or part of it on a usb – I can't seem to find guidance directly related to this.

Kind regards

Aisha

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**From:** Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>

**Sent:** Friday, August 9, 2024 3:04 PM

**To:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Subject:** RE: REMAP-CAP / IRAS 237150 / REC 18/LO/0660 - Query re ISFs

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Dear Aisha

Ultimately, you should follow the archiving arrangements as specified in the study protocol, the SOP of the study site or the SOP of the study sponsor.

Please see the following link for guidance:

<https://www.ct-toolkit.ac.uk/routemap/archiving/>

Thank you

Kind regards

Alex

**Alex Martin**

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**From:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Sent:** Tuesday, August 6, 2024 5:45 PM

**To:** Surrey Borders <[surreyborders.rec@hra.nhs.uk](mailto:surreyborders.rec@hra.nhs.uk)>

**Cc:** ukremap-cap <[ukremap-cap@icnarc.org](mailto:ukremap-cap@icnarc.org)>

**Subject:** REMAP-CAP / IRAS 237150 / REC 18/LO/0660 - Query re ISFs

Dear REC team,

We have a query – our sites that opened over the pandemic have been storing ISF documents electronically (but not an official eISF). We wondered if it was acceptable that these documents be transferred to/archived on a USB rather than retrospectively printing/paper archiving?

As we are an adaptive platform study we have had numerous amendments and PIS/CF as well as protocol changes so we thought we'd ask before mandating superseded documents having to be printed as part of a paper ISF.

For the current flu domains we are running we are providing sites with a paper ISF that sites will continue with.

Kind regards

Aisha



UK REMAP-CAP Trial Management Team

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