

## Greenwood, Hannah

**From:** amendments@hra.nhs.uk <noreply@harp.org.uk>  
**Sent:** 17 January 2025 10:18  
**To:** Alasdair Corfield; Sandu, Pamela  
**Cc:** Greenwood, Hannah  
**Subject:** IRAS Project ID 307862. HRA and HCRW Approval for the Amendment

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Dear Dr Corfield,

<b>IRAS Project ID:</b>	307862
<b>Short Study Title:</b>	EVIS
<b>Amendment No./Sponsor Ref:</b>	SA_09
<b>Amendment Date:</b>	13 December 2024
<b>Amendment Type:</b>	Substantial CTIMP - for review

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment. Minor changes were made to the ICFS following the REC review in order to ensure compliance with GDPR. The approved versions of these documents are listed below:

- Participant consent form [EVIS Sub-Study CF\_V3.0; 09.01.25 CLEAN FINAL], version V3.0, dated 09 January 2025
- Participant information sheet (PIS) [EVIS PIS ICF Personal Legal Rep (Eng, Wales & NI) V5.0 - 09.01.25 CLEAN], version V5.0, dated 09 January 2025
- Participant information sheet (PIS) [EVIS PIS ICF Prof Legal Rep (Eng, Wales, NI) V5.0 - 09.01.25 CLEAN FINAL], version V5.0, dated 09 January 2025
- Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (Eng, Wales & NI) V5.0 - 09.01.25 CLEAN], version V5.0, dated 09 January 2025
- Participant information sheet (PIS) [EVIS PIS ICF V5.0 - 09.01.25 CLEAN FINAL], version V5.0, dated 09 January 2025
- Participant information sheet (PIS) [EVIS PIS Summary V5.0 - 09.01.25 CLEAN FINAL], version V5.0, dated 09 January 2025
- Participant information sheet (PIS) [EVIS Sub-Study PIS\_V3.0; 09.01.25 CLEAN FINAL], version V3.0, dated 09 January 2025

You should implement this amendment at NHS organisations in England and Wales, in line with the guidance in the amendment tool.

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Please contact [amendments@hra.nhs.uk](mailto:amendments@hra.nhs.uk) for any queries relating to the assessment of this amendment.

Kind regards

[Enter Name]

**Health Research Authority**

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**E.** [amendments@hra.nhs.uk](mailto:amendments@hra.nhs.uk)

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