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Trials Manager  
UNIVERSITY OF WARWICK  
WARWICK CLINICAL TRIALS UNIT, WARWICK MEDICAL SCHOOL,  
GIBBET HILL ROAD  
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CV4 7AL  
UNITED KINGDOM

05/05/2022

Dear Trials Manager

**THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031**

Our Reference:	CTA 24637/0010/001-0007
IRAS ID:	1003404
Product:	Ketamine, Morphine sulfate
Protocol number:	SOC.12/19-20
Substantial Amendment Code Number:	Substantial Amendment 04

**NOTICE OF ACCEPTANCE OF AMENDMENT**

I am writing to inform you that the Licensing Authority, having reviewed your application in collaboration with the Research Ethics Committee (where applicable), accepts the proposed amendment to your clinical trial authorisation (CTA), received on 08/04/2022.

This amendment may therefore be made.

If applicable, you should ensure your trial details have been updated on the database where you have registered your trial.

You are reminded that where it is appropriate, the Ethics Committee should also be notified of amendments.

*You are reminded that from 1 January 2022 you will need to comply with the requirements specified in the following guidance, where applicable:*



**# *Import of IMPs from listed countries to GB:***

<https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries>

**# *Supply of IMPs to Northern Ireland:***

<https://www.gov.uk/guidance/supplying-investigational-medicinal-products-to-northern-ireland>

**# *Substantial amendments to clinical trials:***

<https://www.gov.uk/guidance/guidance-on-substantial-amendments-to-a-clinical-trial>

***Any required substantial amendment to your Clinical Trial Authorisation should be submitted and approved as soon as possible and before 1 January 2022.***

Yours sincerely,

**Clinical Trials Unit  
MHRA**