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To Whom It May Concern,

Study title: Paramedic Analgesia Comparing Ketamine and MorphiNe in trauma: PACKMaN
IRAS Project ID: 266748 / 1003404
EudraCT number: 2020-000154-10
Amendment Ref: Substantial Amendment 04

Please find attached the completed amendment tool and the amended documents listed in the table below for review for the above-mentioned trial.

This amendment includes the following updates to the current protocol:


- Ambulance services will now be permitted to recruit patients who may be taken to hospitals that have declined trial participation. Some hospitals have declined trial participation and given the nature of the trial; it will not always be possible for the paramedics to know ahead of enrolment which hospital a patient will need to be taken to. Hospitals declining should not affect patient care and should also not affect the patient's opportunity to be recruited into the study. This was discussed with the MHRA and the protocol updates made in response to their guidance. Please note that as consent is carried out by the research paramedics and not the hospital staff, there will be no issues with obtaining patient consent if the patient is taken to a hospital that has declined trial participation. Research paramedics will be able to obtain consent remotely/electronically (by phone or email), even if the patient is still in hospital. If the patient does not have capacity to consent for a while, then legal representative consent would have been sought prior to obtaining consent from the patient.
- Update to an existing exclusion criterion to make it clear that patients who have self-medicated on opioids/ketamine are still eligible. This consideration is on the basis that PACKMaN is a pragmatic trial and in the real-life population, there is a high chance that self-medicated patients would be treated further by an ambulance crew.

Further clarifications have also been made to the follow-up timeframes and unblinding process and the Qualtrics privacy statement added to the PIL.

Document	Version	Date
Summary of changes document	/	/
PACKMaN Protocol – clean version	5.0	15/03/2022
PACKMaN Protocol – tracked changes version	5.0	15/03/2022
PACKMaN_PIL Patients – clean version	4.0	15/03/2022
PACKMaN_PIL Patients – tracked version	4.0	15/03/2022

Please do not hesitate to contact us should you require any further information.

Kind regards,



Dr Hannah Noordali
Clinical Trial Manager