Authorization Form WMO-research
Delegation based on education, training and work experience

Site number		**Study name**	REMAP-CAP
Site name		**Protocol number (METC/ABR)**	2015-002340-14
PI name		**Sponsor/Verrichter**	UMC Utrecht

By signing below I declare that during the conduct of the above study, trial personnel whose specimen signatures and initials appear below are authorized to perform the study duties as listed in the table 'Range of study duties'. They are qualified[1] and appropriately informed about the study.

I understand that my signature indicates the delegation of tasks and procedures to site staff, but that accountability for the delegated tasks and procedures is retained by myself.

Principal Investigator Signature: _____

Range of study duties				
1. Obtain and sign Informed Consent	5. Sign Queries, DCFs	9. Assess (S)AE's	13. Medication monitoring - 4 eyes principle	17.
2. Complete / Fill-in CRFs	6. Sign certified copies[3]	10. Report SAE's	14. Drug accountability	18.
3. Sign CRFs	7. Update study files	11. Prescription study medication	15.	19.
4. Complete/Fill-in Queries	8. Assess in/exclusioncriteria[4]	12. Administration study medication	16.	20.

Name	**Initials/ Paraph**	**Position**	**Signature**	**Range of study duties[2]**	**Start date**	**Stop date**	**Initials PI**	**Date of delegation**
		Principal Investigator (PI)					Not applicable	Not applicable

[1] For medical staff in UMC Utrecht clinical privileges are documented as described in Procedure Supervision and Authorization A(N)IOS and in Procedure Privilege medical staff.
[2] Fill in the range of study duties that are applicable.
[3] Certified copy: A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original (ICH, E6-R2).
[4] In research with a medicinal product, the in-and exclusion criteria should be assessed by a physician.

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[2] *Fill in the range of stuy duties that are applicable*

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[2] *Fill in the range of study duties that are applicable*