**REMAP-CAP Consent Statement**

**One statement to be completed per consent.**
To be filed in patient medical records alongside copy of signed consent form and patient information sheet used. The purpose of this statement is to ensure the consent process is followed and documented in a GCP compliant manner.

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| **Study Title:** | **Randomised, Embedded, Multifactorial Platform Trial for Community Acquired Pneumonia (REMAP-CAP)** |
| **IRAS Number:** | **237150** | **Protocol Version and Date:** |  |

Before written and informed consent to participate is obtained from the patient or PerLR/ProLR, the study is introduced by a delegated member of the study team using an approved version of the information sheet.

As per protocol and Good Clinical Practice guidelines for clinical research, time is given time to read the information sheet as well as the opportunity to discuss the study in detail with a delegated member of the clinical team, to help them in their decision-making.

The patient/PerLR is given a copy of their signed and dated consent form and associated information sheet and a copy is also filed in medical records.

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| **When is consent being attempted/obtained?** | **Tick** |
| **Prospective (patient)** - prior to enrolment |  |
| **Deferred consent (PerLR/ProLR)** - prior to enrolment |  |
| **Delayed consent** - in an emergency, aim to obtain within 24 hrs after patient enrolment, from PerLR/ProLR |  |
| **Retrospective (patient)** - once patient has regained capacity, within 180 day follow up period |  |

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| **Who is consent being attempted/obtained from?** |
| [ ] Patient**OR**[ ] Tick here if patient does NOT have capacity to consentAssessment of incapacity (i.e. not awake/sedated, delirium etc.): |
| [ ] Personal legal representative (PerLR)**OR**[ ] Tick here if PerLR does NOT have capacity or is not available to consentReason for incapacity: |
| [ ]  **Professional legal representative (ProLR)** [ ] Confirm that ProLR is a clinician or matron who is NOT listed on the study delegation log |
| [ ]  **Delayed consent**[ ] Patient cannot consent, PerLR and ProLR are not available, and enrolment is beneficial for the patient (emergency enrolment with no consent in place) |

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| **How is consent being obtained?**  | **Tick** |
| Written, in person |  |
| Verbal in person, witnessed |  |
| Verbal by telephone, witnessed |  |
| [ ]  **If witnessed, please tick to confirm the witness is independent of the study i.e. not listed on the delegation log. This can be an admin, nurse, clinician etc.**Role of witness/relationship to patient: |  |
| Written, by postDate sent out: Date returned:[ ] Not returned |  |

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| **Which info sheet and consent form is being used?** | **Tick** | **Amendment version (in footer) i.e. NSA12** | **Site version / date (in footer) i.e. V1.0, 23Jun25** | **Language** | **Original filed in ISF?** |
| PIS/CF  |  |  |  |  |  |
| PIS/CF summary (+ copy of full PIS given) |  |  |  |  |  |
| PerLR IS/CF  |  |  |  |  |  |
| PerLR IS/CF summary (+ copy of full PIS given) |  |  |  |  |  |
| Telephone/remote IS/CF |  |  |  |  |  |
| Video CF (+ copy of full PIS given) |  |  |  |  |  |
| ProLR summary + CF |  |  |  |  |  |
| **Date consent completed/signed: Time:** |
| [ ]  Confirm statement boxes on CF are initialled (not just ticked)[ ]  Confirm all names are written in full and signatures completed/dated[ ]  Confirm witness has signed where verbal or telephone/remote consent obtained |
| Please document any CORRECTIONS that have been requested on the CF from either site staff or patient(please ensure these are initialled/dated on the CF): |
| **Were any elements of the study NOT consented to?** (please circle) | Yes | No |
| If Yes, please specify:[ ] Sample collection [ ]  Other: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**[ ] Day 180 follow up |

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| **CONSENT WITHDRAWAL** | **Please circle** |
| Has consent been withdrawn for ALL study procedures?  | Yes | No |
| Has consent been withdrawn for certain elements of the study only? | Yes | No |
| **Date of withdrawal:** |
| Reason, if known/disclosed: |
| Elements withdrawn from, if not the entire study:[ ] Treatment [ ] Day 180 follow up[ ] Further data collection [ ] Further sample collection [ ] Previous samples collected not to be used[ ] Other, please specify: |

**Name of person completing consent statement:** ­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Role:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date**: \_\_\_\_\_\_/\_\_\_\_\_\_\_/\_\_\_\_\_\_\_ (Day/Month/Year)