Consent finding follow-up requirements

These follow-up requirements provide guidance on how various deviations from the Informed consent process, form completion and documentation should be handled. Any follow-up action should be adjusted in line with country requirements as applicable

This column indicates if a PD must be registered also.
PD possibly: might be a PD depending on local law, monitor to provide instruction.

Study	Category	Finding summary	Finding detail	Site Action	PD / NO PD	Monitor Action.
REMAP-CAP	Process	No consent obtained	No informed consent obtained to confirm subject/LAR has agreed to study participation. - subject alive	Obtain subject/LAR consent as soon as possible. After D180: Add no patient consent expected to eCRF	PD	Major PD; escalate to PM. To check/request details of consent process documentation in source. To check/request if informed consent is missing for other patients. If multiple consents missing at site, monitor to escalate within 24 hours to initiate serious breach/data breach assessment by Sponsor. To re-train site and document re-training. To ensure proper documentation of finding in source. To prioritize site for next MV, if still recruitung.
REMAP-CAP	Process	No consent obtained	No informed consent obtained to confirm subject/LAR has agreed to study participation. - subject deceased	In countries with no approved delayed consent process: Obtain personal LAR consent to use subject data as soon as possible. In countries with approved delayed consent process: if required by local law in country, obtain personal LAR consent to use subject data as soon as possible Add no patient consent expected to eCRF	PD	Major PD if no delayed consent process approved in country; To escalate to PM. To check/request consent process documentation in source. If multiple consents missing at site, escalate within 24 hours to initiate serious breach assessment by Sponsor. To re-train site and document re-training. To ensure proper documentation of finding in source.
REMAP-CAP	Process	No patient consent obtained	No patient consent after LAR consent even though subject has the capacity/became capacitated to provide consent – during hospitalisation	Obtain patient consent.	PD	Minor PD; document in SVR/MIAT. To re-train site to always obtain patient consent if patient is capacitated.
REMAP-CAP	Process	No patient consent obtained	No patient consent after LAR consent even though subject has the capacity/became capacitated to provide consent – after hospital discharge prior day 180	Obtain patient consent (remotely). For subjects that remain incapacitated at hospital discharge sites are expected to check at least at day 90 and day 180 if the subject has regained capacity to provide consent, if still alive. Document the reason why no consent was obtained during hospitalization and the attempts made to reach the patient.	Possibly	To check source documentation for consent process description including attempts to reach the patient. To re-train site as required and document re-training. If the patient was reachable, but no consent was obtained - PD. Otherwise, Not a PD
REMAP-CAP	Process	No patient consent obtained	No patient consent after LAR consent even though subject has the capacity/became capacitated to provide consent – after day 180	Document the reason why no consent was obtained during hospitalization and the attempts made to reach the patient after discharge. Add no patient consent expected to eCRF	NO PD	To check source documentation for consent process description including attempts to reach the patient. To re-train site and document re-training. Note: the proposed site action is still under review by the MHRA, and will be applied unless objection is received from the MHRA.
REMAP-CAP	Process	No patient consent obtained	No patient consent after LAR consent; subject permanently incapacitated / deceased	Add no patient consent expected to eCRF	NO PD	To check if data can be used according to country regulations of country where subject was randomized. In case the data cannot be used: escalate to Sponsor PM
REMAP-CAP	Process	No personal LAR consent	No personal LAR consent obtained after professional LAR consent, when the subject remained incapacitated for a prolongued period of time - subject alive	Obtain personal LAR consent Add no patient consent expected to eCRF	PD	Minor PD; document in SVR/MIAT. To check if data can be used according to country regulations of country where subject was randomized. In case the data cannot be used: escalate to Sponsor PM
REMAP-CAP	Process	No personal LAR consent	No personal LAR consent obtained after professional LAR consent - subject deceased	Site to document process and any attempts made to obtain consent/reach out to personal LAR and if they were reached/informed of study participation. Add no patient consent expected to eCRF	Possibly	Minor PD if personal LAR consent is required as per country legislation (after patient death). To check if data can be used according to country regulations of country where subject was randomized. In case the data cannot be used: escalate to Sponsor PM In case of multiple cases: retrain site
REMAP-CAP	Process	LAR consent falsely applied	LAR consent applied for capacitated subject or if source implies subject might be capacitated (possibly moderate subjects for REMAP-CAP)	Obtain subject consent as soon as possible	PD	Major PD if no other critical factors affected the consent process (e.g. contamination risk). In that case, minor PD. To escalate to PM to initiate Serious Breach assessment at Sponsor. To re-train site and document re-training.
REMAP-CAP	Process	Site is defaulting to Professional LAR consent	Professional LAR consent routinely applied for (capacitated) subjects, with no (documented) attempts to obtain personal LAR consent	Site to change process and to use Professional LAR only in situations where no patient/personal LAR consent can be obtained. Obtain patient/personal LAR consent as soon as possible, if not avaiable yet.	PD	Major PD; escalate to PM. To re-train site and document re-training.
REMAP-CAP	Process	Delayed consent falsely applied	Delayed consent applied when prospective consent was possible / treatment start was not urgent / LAR available at time of inclusion / enrolment was not beneficial for the patient / not in line with country regulations.	Obtain LAR/subject consent as soon as possible; inform monitor	PD	Major PD; escalate to PM to initiate Serious Breach assessment at Sponsor. To re-train site and document re-training. To ensure proper documentation of finding in source.
REMAP-CAP	Process	Verbal consent falsely applied	Verbal consent applied when written consent was possible.	Obtain written consent as soon as possible. Document rationale for obtaining verbal consent instead of written consent.	PD	Major PD; escalate to PM to initiate Serious Breach assessment at Sponsor. To re-train site and document re-training.
REMAP-CAP	Process	Witnessed consent falsely applied	Impartial witness does not meet requirements/ process not performed in line with WI ICF.	Obtain valid (witnessed) consent as soon as possible	PD	Minor PD. Major PD if occurs multiple times. To ensure site follows up accordingly; To provide re-training as needed.
REMAP-CAP	Process	Patient consent obtained while patient was not capacitated	Site (source) confirms subject was not capacitated to provide consent for study participation.	Obtain valid (LAR) consent as soon as possible	PD	Major PD; escalate to PM to initiate Serious Breach assessment at Sponsor. To ensure site follows up accordingly; provide re-training as needed.
REMAP-CAP	Process	LAR does not meet requirements	LAR who provided consent to participate in the trial on behalf of the subject does not meet regulatory / protocol / country requirements for LAR.	If no Patient consent was obtained/can be obtained, valid LAR consent should be sought.	PD	Major PD; escalate to PM to initiate Serious Breach assessment at Sponsor. To ensure site follows up accordingly; to provide re-training as needed.
REMAP-CAP	Process	Professional LAR was not independent from trial	Professional LAR has been performing trial-related tasks for this or for another subject, OR Professional LAR is listed on delegation log	Site to compose a NtF to document the cases and the professional LAR to stop any trial-related activities; OR site to involve an alternative independent physician. Site to correct delegation log, if applicable	PD	Minor PD. Major PD if systematic issue at site. To re-train site and document re-training.
REMAP-CAP	Process	Consent obtained by non-qualified / delegated staff	ICF interview/conversation conducted by non-qualified staff: -not delegated -not (adequately) trained -study role not in line with country requirements	Ensure staff is added to the delegation log and collect CV/GCP; document what training/instruction was provided to staff conducting the consent process. Ensure and record PI oversight.	PD	Minor PD if it is a documentation issue, otherwise major PD. To re-train site and document re-training. Finding/required actions to be documented in SVR/MIAT.
REMAP-CAP	Form	Incorrect version of ICF used	Current approved site specific ICF version was not used for consent	If the version used was not approved by EC, site to inform subject/LAR and obtain consent using the correct version. If the version was approved, but is not current, and essential information was not provided to the patient, site to inform subject/LAR and obtain consent using the correct version. If the version was approved, but is not current, but differences are only minor (no impact on safety and privacy), site to inform subject/LAR, but no additional written consent needed.	PD	Major PD if patient was not provided with essential information or version was not approved by EC. To check if this happened for multiple patients. To escalate to PM to initiate serious breach assessment by Sponsor. To re-train site on version tracking and document re-training. To ensure that site removes spare blanko forms of previous ICF versions, and marks the master blank version in the ISF as obsolete. Finding/required actions to be documented in SVR/MIAT. Minor PD if the version was approved, but is not current, and the differences are only minor (no impact on safety and privacy), confirm if site informed subject/LAR
REMAP-CAP	Form	Patient consent obtained though patient did not complete (all) ICF fields	Subject did not complete all fields on Patient consent but only provided signature	Comment expected on ICF why fields are not completed (in source or NtF). If subject was not capable of writing, an investigator judgement/confirmation that subject was capacitated is required. This should be documented in the subject source.	NO PD	To ensure site follows up accordingly; To provide re-training as needed. Sites should be encouraged to add an explanation on the incomplete ICF. Finding to be documented in SVR/MIAT.
REMAP-CAP	Form	incomplete ICF	Only ICF signature sheet filed	Site to confirm/document that full ICF document was always provided to the subject. Site to be instructed to file full ICF document moving forward.	NO PD	To ensure site follows up accordingly; to provide re-training as needed. Sites should be encouraged to add an explanation on the incomplete ICF. Finding to be documented in SVR/MIAT.
REMAP-CAP	Form	incomplete ICF	No date or time completed on ICF	Site to add comment on ICF/NTF to clarify missing information on required fields and to confirm LAR or patient consent was available prior randomization (exception for deferred/delayed consent cases).	NO PD	To ensure site follows up accordingly; to provide re-training as needed. Sites should be encouraged to add an explanation on the incomplete ICF. Finding to be documented in SVR/MIAT.
REMAP-CAP	Form	incomplete ICF	Name LAR/name patient missing on one page whereas it has been included on another page	If identity of subject/LAR is certain and subject/LAR will not visit the hospital soon, site staff can complete missing data on ICF. **Explanation for later addition should be added on ICF and signed and dated by person making the entry.**	NO PD	To note missing data and follow-up requirements for site in visit report / MIAT and follow-up letter. To provide retraining to site staff as needed.
REMAP-CAP	Form	incomplete ICF	Name LAR/name patient missing	Subject still hospitalized: reach out to LAR/Subject and request missing information to be added. Subject discharged: if identity of subject/LAR is certain and subject/LAR will not visit the hospital soon site staff can complete missing data on ICF. **Explanation for later addition should be added on ICF and signed and dated by person making the entry.**	Possibly	PD if identity of subject/LAR is not certain as that would mean no valid consent is obtained for a subject (for example: identity cannot be deferred from source as multiple subjects were enrolled on a date or not listed on subject ID log). To provide retraining to site staff as needed. To add action item to MIAT to review completed ICF during next on-site visit.

REMAP-CAP	Form	incomplete ICF	LAR relation to the patient missing	PI responsibility to confirm LAR validity. Before d180: To reach out to the LAR and document the LAR relation in the source data.	NO PD	To add action item to MIAT to review that site is confirming LAR validity during next on-site visit.
REMAP-CAP	Form	lost/misplaced ICF	The copy of the ICF maintained by the site is untraceable	Site to confirm that consent had been obtained and consent process is documented in source. Site to double-check where ICF could have been lost and to confirm if there is potential the document got outside the hospital. if <D180, site to check with patient if a copy of the patient version can be obtained. if <D180 and no copy can be obtained from patient, seek retrospective consent	PD	Minor PD if no copy of the ICF can be obtained. Major PD if no proof of consent. To escalate to PM to initate data breach/serious breach assessment. To add action item to MIAT to review ICF process documentation / copy of ICF during next on-site visit.
REMAP-CAP	Documentation	No documentation of consent process	Site (consistently) has insufficient documentation of consent process	Site to document site consent process in NtF and file in ISF and provide copy to monitor. Moving forward, consent process to be documented for every subject.	PD	To re-train sites on REMAP-CAP & ICH-GCP ICF process & documentation expectations. To add action item to MIAT to confirm adequate ICF process documentation during next on-site visit.
REMAP-CAP	Documentation	Retrospective documentation of consent process	Consent process is documented with a delay of multiple hours or days after actual time of consent / after trial inclusion.	Site to change process and document consent process on time, and before randomization, if feasible	NO PD	To re-train sites on REMAP-CAP & ICH-GCP ICF process & documentation expectations, if this occurred multiple times. To add action item to MIAT to confirm adequate ICF process documentation during next on-site visit.
REMAP-CAP	Documentation	Limited documentation consent process	Consent process is partially documented	Site to document missing information in NtF.	NO PD	To re-train sites on ICH-GCP ICF process & documentation expectations, if this occurred multiple times. To add action item to MIAT to confirm adequate ICF process documentation during next on-site visit.

general: PDs documented in SVR if identified during MV. Ensure that PDs are documented in eCRF. Actions to be added to MIAT if a form, source or process needs to be updated/re-checked. (Re-)trainings should be documented on a TAL (instructor-led or self-training, where appropriate).