Study Title:	WISDOM: LoW Dose-Intensity vs. Standard Dose-Intensity COntinuous Renal ReplaceMent Therapy in Critically Ill Patients (WISDOM): A Pilot Randomized Trial
Document Title:	Instructions for Completion of Remote Monitoring at the Participating Sites
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1.0 OBJECTIVE

This document outlines the processes to be followed when collecting, de-identifying, and submitting source documents for the WISDOM trial remote monitoring to the WISDOM Coordinating Centre.

2.0 RESPONSIBILITIES

This Standard Operating Procedure (SOP) applies to all site staff members at participating sites in the WISDOM trial who will be involved in collecting, de-identifying, and submitting the source documents for remote monitoring.

3.0 PROCEDURES

3.1 Completing the Source Data Verification (SDV) Tool

The SDV Tool is a document which comprises critical variables from the database that have been selected by the Sponsor/Lead PIs for remote monitoring and source data verification.

The project manager will reach out to participating WISDOM sites and request the completion of the SDV Tool for 2 of the first 5 patients randomized at each site, and 10% of the remaining patients randomized, all of whom will be randomly selected.

The SDV Tool should be completed by the Study Coordinator/Research Nurse involved in the trial using source documents.

Upon completion of the SDV tool, sites need to ensure that the 'completed by' and 'reviewed and approved by' sections on the last page are completed prior to submission to the WISDOM Coordinating Centre. The site Principal Investigator and Research Personnel completing the SDV tool must sign off on the document prior to its submission to the WISDOM Coordinating Centre.

3.2 Source Documents Collection and De-identification

Relevant de-identified source documents will be collected for selected variables:

Form 1: Inclusion and Exclusion Criteria.
Form 3: Baseline – year of birth, weight, hospital admission date & time, ICU admission date & time, baseline serum creatinine.
Form 5: Intervention – CRRT – CRRT Initiation date & time, Study Allocated CRRT Initiation date & time
Form 5: Intervention – Daily Worksheet - CRRT duration (hours), Time in Allocated Target Range, Blood flow rate, Dose (total effluent), Dose (hemofiltration), Hemofiltration – prefilter, Hemofiltration – postfilter, Dose (dialysate), Dose (total mean), Dose (highest hourly), Dose (lowest hourly), Ultrafiltration (total), Fluid balance (total).
Form 6: Outcomes - CRRT Discontinuation date & time, RRT at 90-days, Date of last receipt of RRT, Serum creatinine at 90-days, Death within 90-days, Death date and time.
Form 8: Adverse Events and Serious Adverse Events (SAEs only) - Adverse event type, date of onset, Relationship to study treatment, Expectedness, Stop Date.

Site study staff will collect/make a copy of the relevant source documents and write the participant ID on each source document.

For any source documents that are not in English, sites are asked to circle the appropriate values for verification in the database.

To ensure protection of study participants' personal health information and to ensure compliance with privacy regulations, sites must ensure that all source documents are de-identified prior to submission to the WISDOM Coordinating Centre. Some examples of patient identifiers include: name, initials, address, telephone number, email address, medical record number, health plan beneficiary number, etc.

Please remove all patient identifiers from the source documents prior to scanning and submitting the documents to the coordinating centre.

The process of de-identification may differ depending on whether the site uses paper or electronic source documents. Please follow your site's policies on de-identification of records.

3.3 Submission to WISDOM Coordinating Centre

The completed SDV Tool and de-identified source documents can be sent to the WISDOM Coordinating Centre via the WISDOM REDCap regulatory database under the Monitoring event.

Steps for uploading de-identified documents:
1. Create a new instance of the form (see MOP for details on how to do this).
2. Select 'Communication From the Study Team'
3. Select 'Other' for 'Type of Communication'
4. Enter the date that the documents are being uploaded in the 'Date of Other Communications' field.
5. Upload the documents as one pdf in the 'Upload' field.

6. Enter a description of the document in the description field following the format: 'De-identified source documents for participant <XXX-###> <dd/mmm/yyyy>'.

Sites will inform the WISDOM Coordinating Centre once all the documents for submission have been compiled and submitted through the REDCap database.

If upon review by the coordinating centre, it is determined that identifiers were inadvertently transmitted, all copies will be deleted, and the site will be notified of needed corrections and resubmission of de-identified source data. Sites will also be expected to follow local policy for reporting privacy breaches at their institutions.

3.4 Review of Source Documents through Remote Access to EMR

If preferred, and if allowed at your site, the site team may complete the SDV Tool and submit it to the WISDOM Coordinating Centre as noted above in the regulatory database and then arrange a time for the WISDOM project manager to access the site's EMR remotely to review the source data.

Please contact the WISDOM project manager if your site would like to explore this option.

3.5 Review of Source Documents via Other Means

If sites are not permitted to upload to REDCap or do not have an EMR, or prefer a different method for sharing the de-identified documents, please contact the WISDOM project manager to discuss alternative options that may be available to your site.