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## Work Instruction

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WI No.: REDOX- 201-R01

Title: Delegation of Authority Logs

Referenced SOP: Delegation of Authority # 201-00

Author: Rupinder Dhaliwal, Project Leader      Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Intended Audience: Methods Centre, Research Sites

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### Procedures

The purpose of the Delegation of Authority Log is to ensure that all staff at the participating research site having a material effect on the conduct of the REDOX study are qualified and accountable for relevant duties to ensure proper conduct of the study. The Qualified Investigator (QI) at each site is responsible for maintaining a list of individuals delegated significant study related duties at the site.

1. The Project Leader/delegate will develop a Delegation of Authority Log based on the study protocol in consultation with the Sponsor (Appendix 1).
2. The Delegation Log will list the duties/functions of the research site staff that will be participating in the trial. The staff will include but will not be limited to the following:
  - a. Qualified Investigator (QI) and Sub-QI's
  - b. Research coordinators and research assistants
  - c. Pharmacists
  - d. Dietitians
3. The examples of key delegated tasks listed on the Delegation Log are those which may be delegated by the Qualified Investigator to the site research team and these include but are not limited to the following:
  - Screening subjects for eligibility
  - Performing the informed consent process for eligible patients
  - Obtaining written informed consent
  - Patient enrolment and follow-up
  - Checking eligibility criteria
  - Daily monitoring of patient health, safety and study compliance
  - Data collection including case report form entries, corrections and query resolution.
  - Source documentation maintenance
  - Reporting of Protocol Violations
  - Identification of Serious Adverse Events and documentation
  - Maintenance of Regulatory Documents
  - REB submissions and communications
  - Perform study specific training
  - Performing clinical assessments including SAEs and ICU infection adjudication
  - Confirmation of completeness and accuracy of data collected
  - Maintenance of Product inventory
  - Checking of treatment assignment online
  - Study treatment dispensing & accountability, including maintenance of logs
  - Optimizing delivery of enteral nutrition



- Compliance with the Canadian Clinical Practice Guidelines for Nutrition Support
4. A Sample Delegation of Authority Log that outlines the specific trial-duties related to each discipline of the team members will also be developed by the Project Leader. This sample will assist the Qualified Investigator at each site in assigning of tasks (Appendix 2).
  5. Prior to the start of the trial, the Project Leader will send the Delegation of Authority Log to the QI or the research coordinator/delegate at each site.
  6. The QI at each site will be responsible for the ensuring that the following tasks related to the Delegation of Authority Log are completed and may ask the research coordinator to assist with this:
    - a. Inform members of the site research team about the protocol, the investigational agent(s) and their trial-related duties/functions.
    - b. Assign the responsibilities to the appropriate team members (Refer to Appendix 2).
    - c. Ensure that all team members complete the log
      - i. start date: refers to the date that the staff member starts his/her responsibilities with the study
      - ii. end date: refers to the date that the staff member is no longer associated with the study.
    - d. Ensure that the log is updated regularly over the course of the study.
    - e. Keep a record of the log in the site's regulatory study files.
  7. The research site will be asked to send the completed Delegation of Authority Log to the Project Leader/delegate before enrolment starts. In the event that this is done after enrolment starts, a note will be made by the Project Leader/delegate on the study start up CHECKLIST found in the front of the CERU site specific binder.
  8. The Project Leader/delegate will file the completed Delegation of Authority Logs for each site in the relevant site specific binder, under Qualification of Site.
  9. The Project Assistant will remind the research sites, at every 6 month intervals, to send in updated logs, if applicable. This will be done via email and/or newsletter reminders.
  10. Outstanding signatures on the Delegation of Authority Log will be followed up during monitoring visits.



Appendix 1: Delegation of Authority Log & Key Delegated Tasks



# Delegation of Authority Log

This log is used by the Qualified Investigator (i.e. Site Investigator) to indicate the Site Staff that have a material effect on the conduct of the Study and to whom the Investigator has delegated significant Study related duties/tasks. The signatures and details on this log will also facilitate tracking of edits/changes of the Site records. This log is to be kept by the Qualified Investigator and the Sponsor.

Name of Qualified Investigator: \_\_\_\_\_ Signature of Qualified Investigator: \_\_\_\_\_

Print Name	Signature	Initials	Study Role (Qualified Investigator*, sub-QI*, Research Coordinator (RC), Pharmacist, Technician, Dietitian)	Key Delegated Tasks (see next page)	Dates	
					Start	End

\*Qualified Investigator: the Site Investigator responsible for the conduct of the REDOXS<sup>®</sup> study at your site.

\*Sub QI: Investigator other than the Qualified Investigator that is responsible for tasks related to the REDOXS<sup>®</sup> study at your site.

## Key Delegated Tasks

Number	Reference	Key Delegated Tasks
1		Screening subjects for eligibility
2		Performing the informed consent process for eligible patients
3		Obtaining written informed consent
4		Patient enrolment and follow-up
5		Checking eligibility criteria
6		Daily monitoring of patient health, safety and study compliance
7		Data collection Includes: <ul style="list-style-type: none"> <li>❖ Case Report Form entries</li> <li>❖ Case Report Form corrections</li> <li>❖ Data query resolution</li> </ul>
8		Source documentation maintenance Includes: <ul style="list-style-type: none"> <li>❖ Study worksheets, checklists, monitoring sheets</li> <li>❖ Data from electronic &amp; hard copy medical chart</li> </ul>
9		Reporting of Protocol Violations
10		Identification of Serious Adverse Events and documentation
11		Maintenance of Regulatory Documents
12		REB submissions and communications
13		Perform study specific training
14		Performing clinical assessments including SAEs and ICU infection adjudication
15		Confirmation of completeness and accuracy of data collected
16		Maintenance of Product inventory
17		Checking of treatment assignment online
18		Study treatment dispensing & accountability, including maintenance of logs
19		Optimizing delivery of enteral nutrition
20		Compliance with the Canadian Clinical Practice Guidelines for Nutrition Support

## Appendix 2: Sample of Key Delegated Tasks & Delegation of Authority Log

### Sample: Key Delegated Tasks

Study Role	Reference Number	Key Delegated Tasks
Qualified Investigator and Sub Qualified Investigator	5	Checking eligibility criteria
	2	Performing the informed consent process for eligible patients
	3	Obtaining written informed consent
	6	Daily monitoring of patient health, safety and study compliance
	10	Identification of Serious Adverse Events and documentation
	14	Performing clinical assessments including SAEs and ICU infection adjudication
	15	Confirmation of completeness and accuracy of data collected
Research Coordinator	1	Screening subjects for eligibility
	5	Checking eligibility criteria
	2	Performing the informed consent process for eligible patients
	3	Obtaining written informed consent
	4	Patient enrolment and follow-up
	6	Daily monitoring of patient health, safety and study compliance
	7	Data collection, includes: <ul style="list-style-type: none"> <li>❖ Case Report Form entries</li> <li>❖ Case Report Form corrections</li> <li>❖ Data query resolution</li> </ul>
	8	Source documentation maintenance Includes: <ul style="list-style-type: none"> <li>❖ Study worksheets, checklists, monitoring sheets</li> <li>❖ Data from electronic &amp; hard copy medical chart</li> </ul>
	9	Reporting of Protocol Violations
	10	Identification and reporting of Serious Adverse Event and documentation
	11	Maintenance of Regulatory Documents
	12	REB submissions and communications



Study Role	Reference Number	Key Delegated Tasks
Research Coordinator	13	Perform study specific training
	14	Performing clinical assessments including SAEs and ICU infection adjudication
	19	Optimizing delivery of enteral nutrition
	20	Compliance with the Canadian Clinical Practice Guidelines for Nutrition Support
Pharmacist/ Pharmacist Technician	9	Reporting of Protocol Violations
	16	Maintenance of Product inventory
	17	Checking of treatment assignment online
	18	Study treatment dispensing & accountability, including maintenance of logs
Dietitian	19	Optimizing delivery of enteral nutrition
	20	Compliance with the Canadian Clinical Practice Guidelines for Nutrition Support.

## Sample: Delegation of Authority Log

This log is used by the Qualified Investigator (i.e. Site Investigator) to indicate the Site Staff that have a material effect on the conduct of the Study and to whom the Investigator has delegated significant Study related duties/tasks. The signatures and details on this log will also facilitate tracking of edits/changes of the Site records. This log is to be kept by the Qualified Investigator and the Sponsor.

Name of Qualified Investigator: \_\_\_\_\_

Signature of Qualified Investigator: \_\_\_\_\_

Print Name	Signature	Initials	Study Role (Qualified Investigator*, sub-QI*, Research Coordinator (RC), Pharmacist, Technician, Dietitian	Key Delegated Tasks (see next page)	Dates	
					Start	End
			Qualified Investigator	2,3,5, 6,10,14,15		
			Sub- Qualified Investigator	2,3,5, 6,10,14,15		
			Research Coordinator	1, 2, 3, 4,5,6,7,8,9,10,11,12,13,14,19 & 20		
			Pharmacist	9,16,17,18		
			Pharmacist Technician	15		
			Dietitian	19, 20		

\*Qualified Investigator: the Site Investigator responsible for the conduct of the REDOX<sup>®</sup> study at your site.

\*Sub QI: Investigator other than the Qualified Investigator that is responsible for tasks related to the REDOX<sup>®</sup> study at your site.