

The Issue

To be compliant with the Good Clinical Practice: Consolidated Guideline, International Conference on Harmonization (ICH) Topic E6, Health Canada, all participating sites and the sponsor MUST demonstrate that the:

Site Investigator (also called Qualified Investigator)

- **Is qualified by education, training, experience to assume responsibility for the proper conduct of the trial, should meet all qualifications specified by the regulatory requirements, and should provide up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, Research Ethics Board and/or the regulatory authorities (GCP section 4.1.1)**
- **Should ensure that all persons assisting with the trial are adequately informed about the protocol, investigational products and their trial related duties and function (GCP 4.1.5).**

Solution

To ensure that we are all compliant with these guidelines, we will need the following documentation from you as soon as possible:

- 1) Completed **Delegation of Authority Log** with the key delegated tasks assigned to the appropriate persons involved in the REDOXS[®] Study. Please refer to the Sample Key Delegated tasks and Sample Delegation of Authority Logs (attached) on how to fill out the log.
- 2) An updated **Curriculum Vitae (CV)** of your Qualified Investigator.

What to do

1. Complete the **Delegation of Authority Log** by identifying each person that is involved in the conduct of the study and to whom the Qualified Investigator has delegated the key tasks.
2. Each person assigned to the study has to sign and initial the log with the effective start date. End date will be the date the person is no longer associated with the study.
3. Refer to the **Sample of Key Delegated Tasks and the Sample Delegation of Authority Log**. If you agree with the allocation of the tasks on this sample, you may use this as a template or you may make changes to reflect the correct roles assigned to each task.
4. Obtain the most updated **Curriculum Vitae** of your Qualified Investigator (Site Investigator).
5. Fax a copy of the completed **Delegation of Authority Log** and **CV** to Suzanne Biro, Project Assistant, to 613-548-2428.