



NOTE TO FILE

Date: April 23, 2021

RE: Clinical Trials and Research Laboratory Staff Training

All CT&R lab staff are trained laboratory personnel. As such, no additional training is required for basic specimen processing, packaging or shipping.

When protocol requires specialized training for a process or procedure that is not already part of the Standard Operating Procedures, training is identified by the laboratory Technologist II's. The specialized processing procedure and sign-off sheet is placed in a training binder for review and sign off by all Clinical Trial and Research staff. Once all staff have completed the training/review and signed that they understand the processing/handling requirements it is removed from the training binder and placed with the study documents for retention. For digital training a sign off sheet is provided for sign-off. The sign-off sheet is retained with other study documents. A review of the specialized training happens by the Laboratory Technologist II's and follow-up with individuals who have not completed the training occurs.

Specialized training documents are retained with the study specific documents for the life of the study plus 25 years.

Christine Yamniuk
APL, Director, Integrated Programs

Date:

May 17, 2021

Michael Mengel
APL, North Sector Medical Director

May 03, 2021