Value of Partnership Between Clinical Research and Clinical Laboratory Teams: Achieving Seamless Specimen Processing

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Introduction

A major aspect of a clinical research study is the collection of blood, body fluids and tissues for analysis. Research specimens are required throughout the course of the clinical trial to evaluate participant safety as well as treatment efficacy.

Research specimens must be handled according to the research protocol from the time specimens are obtained to the time they are shipped. Some of these procedures are simple and straight forward, others involve several hours of preparation before shipping. Each procedure must be followed to maintain specimen integrity. If any specimen is not correctly processed, it may impact the study results even to the point of disallowing the study patient to continue participation. Research specimen processing may require additional equipment not normally used in the clinical laboratory such as a refrigerated centrifuge and ultra low freezer.

Research is an important part of Lehigh Valley Health Network's mission. The Network Office of Research and Innovation (NORI) at Lehigh Valley Health Network (LVHN) conducts clinical trials in many therapeutic areas:

- Neurology
- Medicine
- Cardiology
- Surgery
- Burn
- OB GYN
- Emergency Medicine
- Adult and Pediatric Oncology
- Pediatrics
- Infectious Diseases
- Investigator Initiated

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HNL/LVHN-NORI Partnership

Recognizing a need for dedicated laboratory personnel, the clinical research team at NORI within LVHN partnered with Health Network Laboratories (HNL) to better manage specimen handling.

NORI has established a team of experienced medical technologists who coordinate the laboratory aspects of clinical trials at LVHN. The NORI lab coordinators handle research specimens from phlebotomy to shipping.

HNL supplies laboratory space dedicated to support NORI research projects within three of their Rapid Response Lab locations in the network – Cedar Crest, 17th Street and Muhlenberg.

Each location has:

- bench work area
- 4°C refrigerated centrifuge
- -70°C ultra low freezer
- access to dry ice for shipments

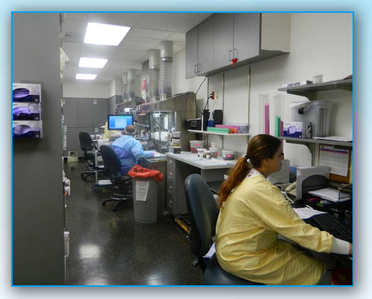
In addition to specialized equipment, NORI lab coordinators have access to refrigeration (2° - 8°C) and -20°C freezers if needed.

Local Lab Testing for Research

In addition to specimens that are shipped to a central laboratory, some research studies also involve laboratory testing done by the in-house local laboratory. Test results maybe needed immediately to determine eligibility, prior to a study procedure or as "safety" labs to evaluate a patient status. Most of these tests are done by HNL in the Rapid Response Labs on a stat basis. HNL provides stat couriers to transport research specimens to the core lab when special testing is needed. A separate account system has been developed by HNL to assure the proper billing mechanism is in place for research specimens. HNL specimen entry personnel make sure research patients get registered properly, with results reported to the research office.

Tissue Specimens for Research

Oncology research involves coordinating patient surgery and pathology specimen handling within research protocol requirements. HNL pathology works closely with NORI lab coordinators to obtain tumor tissue specimens for research. Archival tissue is used as well as fresh tissue samples. NORI lab coordinators request archival paraffin blocks for research. HNL pathology checks for availability of the specimen, selects the appropriate block according to the protocol and provides access to the pathology report. Special processing requirements may be needed for studies that require fresh tissue samples obtained directly from the operating room. In these cases, NORI lab coordinators provide the protocol instructions to HNL pathology. They work closely together to obtain and prepare a quality tumor tissue specimen for research.



Conclusion

Involving MTs in clinical research, with the additional provision of access to laboratory space and equipment, maintains the quality and integrity of research specimens. The partnership of HNL and LVHN-NORI is a viable model that can be replicated in other institutions for seamless processing of research specimens.