Authorizing Prescriber(s)

LHO - Durham Region Cancer Center Physicians designated as Principal Investigator (PI) or Sub-Investigator (SI) per research protocol.
LHO – Clinical Trials Research Program Physicians designated as Principal Investigators (PI) or Sub-Investigator (SI) per research protocol.

This directive is not to be used to replace physician initiated orders for any clinically evolving events, adverse events or in-patient management whether or not these events are related to the Clinical Trial.

Authorized to Whom

Clinical Trials Nurses, in the Clinical Trials Department at Lakeridge Health (LH) and/or the Durham Region Cancer Center (DRCC) that have the knowledge, skill, judgement and training to conduct clinical trials Laboratory Investigations as set out per protocols.

Co-implementers:
Medical Laboratory Technologists, Medical Laboratory Technician/Assistant, and/or Phlebotomist employed at LH who have the knowledge, skill and judgement.

Patient Description/Population

Adult patients over 18 years of age who are registered in screening and/or enrolled in a Clinical Trial through the Clinical Trials Research Program and/or Durham Region Cancer Center.

Order and/or Procedure

These procedures are not presented in sequential order; any one of or combination of the order/procedure below may be performed by a Clinical Trials nurse after reviewing the Schedule of Assessments contained in the Protocol.

A) Ordering of safety monitoring laboratory investigations only, which are required as detailed per visit/cycle as per Protocol

Indications to the Implementation of the Directive

Any patient registered in screening and/or enrolled in a clinical trial where laboratory investigations are required as per Protocol of the Clinical Trial that is being conducted at LH and/or DRCC.

Contraindications to the Implementation of the Directive

This directive must not be implemented in any of the following circumstances:

- The Patient who has not provided informed consent to participate in the Clinical Trial for which the laboratory investigation is being performed for.

- The Patient who withdraws their informed consent from the clinical trial for which the trial laboratory investigation is being performed for.

Consent

The Clinical Trials Nurse implementing the medical directive must ensure the patient has formally consented, through the informed consent process, to participating in a Clinical Trial at LH or DRCC.

Documentation Requirements

In addition to standard documentation practices, the Clinical Trials Nurse implementing this directive must document the following in the order section of the patient's health record:

- The name of this medical directive
- The procedure and/or orders that were completed
- The name of the implementer
- The date and time (unless documenting electronically)
- Legible signature of implementer including credentials (unless documenting electronically)
- A copy of this Medical Directive is placed with the Site File with the corresponding Protocol for which ordering the laboratory investigation is being carried out.
- Co-implementers will document in the patients' health record as per standard documentation practices

Review/Evaluation Process

This medical directive is to be reviewed every 2 years by the Clinical Trials Quality Council.

References

http://www.cmlto.com/index.php?option=com_content&view=article&id=1365&Itemid=563

http://www.cno.org/globalassets/4-learnaboutstandardsandguidelines/prac/learn/webcasts/orderswebcast.pdf

http://www.cno.org/globalassets/docs/prac/41071_decisions.pdf

http://www.cno.org/globalassets/docs/prac/41075_authorizingmech.pdf

http://www.cpso.on.ca/Physicians/Policies-Guidance/Policies/Delegation-of-Controlled-Acts

http://www.cpso.on.ca/Physicians/Policies-Guidance/Policies/Test-Results-Management