DIABETES & ENDOCRINOLOGY

PA Competency Checklist – Addendum: Research Skills 4.01

PA Name:	Does the PA meet the Standard? (initial + date)		Plan
	Y	N	

CORE SKILLS

Demonstrates a strong understanding of Research SOP.			
Knowledgeable of Good Clinical Practices (GCP) guidelines.			
Demonstrates a good understanding of informed consent procedures as per site SOP and GCP guidelines.			
Obtains relevant health history as applicable for the research protocol.			
Utilizes study specific eligibility criteria for the correct recruitment of study participants.			
Assessing Eligibility – approval of subjects for a clinical research study.			
Document and Management of AEs and SAEs.			
Reporting and review of labs, ECGs and Diagnostic Reports • Timely sign-off/documentation of lab reports • Documentation of assessments – clinically significant and not clinically significant • Escalation of STAT lab reports to PI			
Glucose Clamping, including; • Performing preparation for glucose clamping • Performing glucose clamping process – including raising and lowering patient's plasma glucose concentrations • Documenting activities related to glucose clamping			
Successfully completed the Investigator Mentorship Program, including: • GDP and review of appropriate research documentation • HC Division 5 training			

Name of PA: NAME Signature:_____ Date: ____/_____/_____

Name of Primary Supervising Physician: NAME Signature_____ Date: ____/_____/_____

Name of Supervising Physician: NAME Signature_____ Date: ____/_____/_____

Name of Supervising Physician: NAME Signature_____ Date: ____/_____/_____

Name of Supervising Physician: NAME Signature_____ Date: ____/_____/_____

PA Medical Directive – Addendum: Research Skills 4.01

Number 4.01

Activation Date: Date **Review due by:** Annual Basis

Sponsoring/ Contact Person(s)
Name , Primary Supervising Physician
Name, Supervising Physician
Name, Supervising Physician
Name, Supervising Physician
Name, Supervising Physician

Orders: **Appendix Attached** **Title: Order Table**

(PA NAME) PA may implement orders for and/or perform diagnostic and therapeutic procedures as ordered on the appended Order Table, in accordance with the conditions identified in this directive. Orders for procedures include those for

- Informed consent procedure
- Approval of Subjects for Study Participation
- Document and Management of AEs and SAEs
- Reporting and Review of Labs, ECGs and diagnostic imaging
- Glucose Clamping

Recipient Patients:

- Adult patients ≥ 18 yrs of age who (or, >16 years old with physician consent) have been referred to for diabetes care, related metabolic disorders cardio-metabolic risk management, or other endocrine disorders.
- Registered to any supervising physician who has approved this directive and
- Being referred for consultation by an physician to a supervising physician who has approved this directive
- Patients referred by advertisements to any physician.

Authorized Implementers: **Appendix Attached** **Title: Addendum Research skills 4.01 Competency Checklist**

PA(s) who have successfully completed the Competency Assessment, have reviewed the directive and have been authorized to practice under medical directives.

Where PAs are authorized to implement physician orders pursuant to this directive, the following co-implementers may carry the orders out in accordance with their regulatory authority and role descriptions : RN, RD, CRC

Indications: **Appendix Attached** **Title: Order Table**

1. Patients must have a working diagnosis given by the PA's supervising physician and/or have presenting complaints as identified on the appended Order Table,
2. Unless noted on the Order Table:
   a. Diagnostic orders may be implemented for patients registered to a supervising attending physician and those referred for consultation who will be registered to a supervising physician.
   b. Therapeutic orders may only be implemented for registered patients.
3. Unless noted on the Order Table, indications for medications are in accordance with the following medication references:
   - Compendium of Pharmaceutical & Specialties (2013)[1]
   - Canadian Diabetes Association, Clinical Practice Guidelines, (2013)[2]
   - American Diabetes Association, Clinical Practice Recommendations, (2013)[3]
   - AACE Medical Guidelines for Clinical Practice for the Management of Diabetes Mellitus © (2011)[4]
4. See appended Order Table for specific presenting complaints, working diagnoses and indications

Contraindications:

Patient refuses procedure. See appended Order Table for specific contraindications.

Guidelines for Implementing the Order / Procedure: **Appendix Attached** **Title: Order Table**

See appended Order Table.

Documentation and Communication:

(PA NAME) PAs will document medication administered and/or therapeutic intervention in the patient record.

Review and Quality Monitoring Guidelines:

Staff identifying any untoward or unintended outcomes arising from implementation of orders under this directive, or any issues identified with it, will report these to Dr. or supervising physicians as soon as possible for appropriate disposition. This does not include untoward or unintended outcomes or issues that are possible clinical sequelae regardless of whether a direct order or directive is used.

Administrative Approvals

PA : Medical Directive 4.00 is approved by the Primary Supervising Physician, Dr and all other physicians acting as supervising physicians for the PA as listed and signed as authorizers.

[1] Canadian Pharmacist Association. *Compendium of Pharmaceuticals and Specialties: The Canadian Drug Reference for Healthcare Professionals.* Ottawa, ON: Canadian Pharmacist Association, 2013.
[2] Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Can J Diabetes 2013;37(suppl 1):S1-S212.
[3] American Diabetes Association. "Clinical Practice Recommendations". *Diabetes Care*. 36.1 (2013): S1-108.
[4] American Association of Clinical Endocrinologists. "American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Developing a Diabetes Mellitus Comprehensive Care Plan." *Endocr Pract.* 17.1 (2011): 1-53.

Order Table
Medical Directive **Addendum: Research Skills 4.01**

	Indications / Contra-indications and Guidelines
Informed Consent Procedure	**Indications** Adult patient 18 yrs or older (or as per study protocol) Diagnosed with either endocrine or metabolic condition who is referred to the study by a supervising physician or patient who is responding to an advertisement **Contra-indications** Patient refusal **Guidelines** PA will verify the contents of the IC. The PA will provide potential subjects/ enrolled subjects with REB and/or Health Canada approved Informed Consents and any new information that may be relevant to the subject's participation. PA will respond to the subjects questions concerning the protocol and IC. The PA will document the involvement in the IC process as per research SOP.
Approval of Subjects for Study Participation	**Indications** Adult patient 18 yrs or older (or as per study protocol) Diagnosed with either endocrine or metabolic condition who is referred to the study by a supervising physician or patient who is responding to an advertisement **Contra-indications** Patient refusal Does not meet study specific requirements (Screen Failure) **Guidelines** The PA will review the preliminary and completed inclusion and exclusion checklist , along with all supporting documents and concomitant medications to determine a subject's eligibility for a clinical research study. Approval status will be documented by the PA by signing the inclusion and exclusion checklist and appropriate necessary documents.

Document and Management of AEs and SAEs	**Indications** Adult patient 18 yrs or older (or as per study protocol) Diagnosed with either endocrine or metabolic condition who is referred to the study by a supervising physician or patient who is responding to an advertisement **Guidelines** PA is responsible for ensuring that AEs and SAEs are identified, documented, reviewed, assessed and reported within a timely manner. AEs are documented and assessed from the time the subject signs informed consent, through follow-up or lost-to-follow unless otherwise required by protocol. Subjects are to be questioned about any potential AE that might have occurred throughout the study. The onset date and time, severity, frequency and outcome of the AE will be documented. The causality and action to investigational product will also be documented. The PA will make an assessment of AEs and SAEs for clinical significance, causality and document action taken with respect to the investigational product. The PA will ensure that all ongoing AEs and SAEs are followed until resolution. All serious AEs will be escalated to the PI, or supervising physician to manage as per LMC research SOP.
Reporting and Review of Labs, ECGs and diagnostic imaging	**Indications** Adult patient 18 yrs or older (or as per study protocol) Diagnosed with either endocrine or metabolic condition who is referred to the study by a supervising physician or patient who is responding to an advertisement **Guidelines** The PA is responsible for reviewing labs, ECGs and diagnostic reports for research subjects. The PA will document review with timely sign-off of the reports. The PA will document their assessment on the lab report by determining clinical significance for all out of range results. The PA is responsible for providing adequate medical care and informing potential/ enrolled subjects of clinically significant findings that require medical care for intercurrent illness(es) and ensuring appropriate follow-up of care. Guidance from supervising physicians will be utilized when necessary.

Glucose Clamping	**Indications** Adult patient 18 yrs or older (or as per study protocol) Diagnosed with either endocrine or metabolic condition who is referred to the study by a supervising physician or patient who is responding to an advertisement **Contra-indications** Patient refusal **Guidance** Plasma glucose concentration is raised using glucose and lowered using insulin as per protocol and PI discretion. Specific protocol to raise and lower blood glucose values will be outlined in study directives for the applicable study.

Approving Physician(s)/Authorizer(s):	
Primary Supervising Physician: Name _____ *Signature*	_____ *Date*
Supervising Physician: Name _____ *Signature*	_____ *Date*
Supervising Physician: Name _____ *Signature*	_____ *Date*
Supervising Physician: Name _____ *Signature*	_____ *Date*
Supervising Physician: Name _____ *Signature*	_____ *Date*