

In This Issue

- Clinical Engineering Services for Research
- Study Request Form and TRAQ DSS FORM
- Inspection
- Calibration and Maintenance records



Clinical Engineering Services for Research:

To ensure that all medical and research equipment and devices are safe for use on patients and research participants and used by Kingston Health Sciences Centre (KHSC) staff, all electrically-powered, electro-medical or non-electro-medical equipment and devices **MUST** be inspected and tested prior to use in KHSC. Inspection occurs via three channels in KHSC: Clinical Engineering Services, Medical Physics or Plant Services. When applicable, equipment and devices will have preventive maintenance schedule established and followed that will ensure that they remain safe.

Electro-medical equipment and devices (*hospital-owned, researcher-owned or industry owned*) used for the purpose of approved clinical research at KHSC (KGH Site and/or HDH Site) **MUST** have an electrical inspection completed by KHSC's Clinical Engineering Services to ensure CSA codes and standards are upheld at the Hospital as per KHSC-KGH's Administrative Policy 04-027 and KHSC-HDH's Administrative Policy 02-03.

<http://www.kgh.on.ca/research>

Contact:

kghri@kgh.kari.net

(613) 549-6666, ext. 3344

Clinical Engineering Services
Kingston Health Sciences Centre
Chris.Scott@kingstonhsc.ca
Manager, Clinical Engineering

STUDY REQUEST FORM AND TRAQ DSS FORM

Researchers need to submit a “KHSC Clinical Engineering Services Study Request Form”. The completed form must be **ATTACHED** to your TRAQ DSS FORM prior to submission to ensure that your clinical trial/research project is processed in a timely manner and to minimize any delays in initiating your clinical trial/research project once all approvals have been obtained. Please remember to check off “KGH-Clinical Engineering” and/or “HDH-Clinical Engineering” on the Approvals Tab of your TRAQ DSS FORM so that KHSC Clinical Engineering Services can sign off on your TRAQ DSS FORM based on the site(s) identified. We strongly encourage researchers to contact KHSC

Clinical Engineering Services in the early stages of their protocol and budget development to ensure that their studies are set up properly and researchers are aware of any clinical engineering services costs associated with their research. Researchers are responsible for covering all costs associated with their clinical trial/research project above and beyond the standard of care.

The “*KHSC Clinical Engineering Services Study Request Form*” can be found at this link under “Forms”: <http://www.kgh.on.ca/research/researchers-staff-trainees/policies-and-forms>.

Once your TRAQ DSS FORM is submitted, the KHSC Clinical Engineering Services will be automatically notified of your TRAQ DSS FORM and KHSC’s Clinical Engineering Department Manager (Chris Scott) will review your *KHSC Clinical Engineering Services Study Request Form* and either approve “as is” or reach out to you for further clarification, if required. To contact KHSC’s Clinical Engineering Services regarding your TRAQ DSS FORM, please reach out Chris Scott at KHSC-KGH Site ext. 2260 or Chris.Scott@kingstonhsc.ca.

INSPECTION

Equipment and devices will be inspected and tested by the appropriate service department (Clinical Engineering Services (CS), Medical Physics (MP) or Plant Services (PS)) within KHSC prior to use. Inspections and testing occurs within the service department’s area. Large items that cannot be practically delivered to the service department’s area will be inspected on site. The appropriate service department (CS, MP or PS) needs to be notified in advance by the manager or delegate of the clinical department or by the principal investigator for research designated areas.

Before any piece of equipment and/or device is used for patient care or for research purposes, the manager or delegate of clinical department or the principal investigator for research designated areas, will ensure that all equipment and devices arriving at KHSC from any source has been inspected by locating the appropriate tagging method. A dated inspection sticker will be attached to all CE and PS equipment and devices. In addition, for hospital-owned equipment and devices, CE will attach a control number sticker while PS will engrave an identifier on the actual piece of equipment or device.

CALIBRATION/MAINTENANCE RECORDS

For electro-medical equipment and devices (*hospital-owned or researcher-owned*), KHSC’s Clinical Engineering Services may be able to provide this service on a fee-for-service basis. Hospital-owned equipment requiring additional calibration/certification above and beyond standard calibration required for Hospital Accreditation, requires early consultation with KHSC’s Clinical Engineering Services in advance of your research project initiating. Researchers are responsible for covering all costs associated with these types of requests. Calibration and maintenance records for all sponsor-owned equipment **MUST** be handled by the Sponsor/CRO.