POLICY AND PROCEDURE MANUAL
DUKE UNIVERSITY HEALTH SYSTEM

Clinical Engineering Policy CE-035

IRB Research Instrumentation

POLICY: Clinical Engineering staff shall apply the following guidelines to devices that are under IRB protocols not part of the Clinical Engineering inventory. Clinical Engineering staff will not accept equipment for use unless these conditions are met.

PURPOSE: This policy is for defining a consistent response, by Clinical Engineering staff, to the request for medical instrumentation to be used on Duke University Health System patients that is not FDA approved, or tested by an approved independent testing laboratory.

PROCEDURE: Medical instrumentation will be defined as any instrumentation and / or technology that is to be used to diagnosis, treat, monitor, or gather data for research, from human beings. This includes all devices not FDA approved or listed by UL, CE, ETL, CSA, or MET. This also applies to any combination of devices that are individually approved and/ or listed but are not an integral part of a production product for sale by a current medical equipment manufacturer.

- Devices that are not FDA approved must be covered under a current IRB and a copy of the IRB documentation should be presented with the equipment before an inspection procedure is performed.
- If the technology uses AC current in the range of 100-130 volts at 50-60 Hz, an electrical leakage test and ground competency test will be performed. The instrumentation must comply with the previously established leakage current and ground resistance limits for the area of use. If there are multiple devices that require AC power the cumulative leakage current and ground resistance limits must be addressed and the value may not exceed the limits established in the current regulatory standard. If the instrumentation uses 3 phase power or AC voltages other than listed above a ground competency test will be performed.
- A preoperative checkout will be performed to define the operational state of the technology before going into use. Clinical Engineering may choose to require the check-out procedure be performed by the equipment manufacturer if needed. If the equipment passes this procedure, a Clinical Engineering maintenance inspection sticker will be affixed to the case of the device that identifies an approved time interval, the testing technician, and the tests performed.

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