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1. PURPOSE

1.1. This policy establishes the criteria and process for human subjects research involving electrical equipment.

2. DEFINITION

2.1. Electrical equipment as applicable to this policy is defined as equipment that plugs into the wall while in contact with human subjects.


3. EXEMPTION

3.1. The following electrical equipment are exempt from this policy:


- 3.1.1. Battery powered devices
- 3.1.2. Computers used for completion of surveys or other research activities
- 3.1.3. Commercially purchased equipment that has not been substantially modified and is being used for their intended purpose per manufacturer specifications.
- 3.1.4. Examples of equipment exempt from this policy include:
 - Treadmills
 - DXA
 - EEG
 - Biopac
 - EMG
 - Motion Analysis
 - Virtual Reality

4. POLICY

- 4.1. If a human subjects research protocol conducted at Marquette University involves subject contact with electrical equipment, the equipment is subject to this policy.
- 4.2. Each protocol must include sufficient information for the IRB to determine whether electrical safety is an issue. The protocol must identify all electrical equipment, as defined above, used in subject contact. When available, manufacturer, model number, and serial number (if known), and manufacture or purchase date must be provided. The protocol must describe how the equipment is to be used, as well as its location.

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- 4.3. Initial electrical safety testing must be conducted prior to human subjects interacting with the equipment.
- 4.4. Continued electrical safety testing must occur every 5 years after the initial date of testing and may be required more frequently if deemed necessary by the IRB. Copies of safety testing must be provided to the IRB upon request.
- 4.5. Equipment not located at Marquette
- 4.5.1. Equipment owned by and used at a location other than Marquette does not require submission of electrical safety testing documentation.
- 4.5.2. Equipment owned or created by Marquette and used at a location other than Marquette requires electrical safety testing as described above.
- 4.5.3. Equipment owned or created by personnel at another institution and used at another institution requires testing/approval per that institution's policy. The IRB may request documentation of the other institution's policy and test results. If the IRB has safety concerns regarding the device, additional testing or inspection may be required.
- 4.5.4. Any equipment used in a research protocol where an authorization agreement has been executed for Marquette to rely on another institution does not require electrical safety testing.
- 4.6. Testing Devices
- 4.6.1. Contact the ORC to request a test.
- 4.6.2. If a device does not pass electrical safety testing it is the responsibility of the investigator to remedy any defects and have the equipment retested.
- 4.6.3. Alternate testing devices may be used. Consult with the ORC.
- 4.7. The ORC may require additional inspection/testing in certain circumstances. These circumstances may include, but are not limited to, protocol audit by the ORC, HHS/OHRP, or funding agency, adverse event or unanticipated problem related to equipment, participant complaint regarding equipment, investigator noncompliance, or other issues related to the protection of human subjects in research.
- 4.8. Waiver of Electrical Safety Testing

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4.8.1. In the event that electrical equipment as defined by this policy cannot be tested by university owned equipment, and other means of testing cannot be located on campus, the ORC has the ability to grant a waiver of electrical safety testing for a specific piece of equipment.